Efficacy of a peer-led exercise and education programme combined with a therapeutic relationship to manage pain in rural amaXhosa women living with HIV/AIDS compared to a therapeutic relationship alone

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Declaration

I, Kirsty Nontsikelelo Jackson, hereby declare that the work on which this thesis/dissertation is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university. I authorise the University to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever.

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Abbreviated Terms

6MWT	Six-minute walk test
6MWD	Six-minute walk distance
AIDS	Acquired Immune Deficiency Syndrome
ART	Anti-retroviral therapy
ARV	Anti-retroviral
AZT	Zidovudine
BPI	Brief Pain Inventory
BDI	Beck Depression Inventory
CBT	Cognitive behavioural therapy
CDSMP	Chronic Disease Self-Management Programme
CES-D	Center for Epidemiological Studies Depression Scale
CHC	Community Health Centre
CONSORT	Consolidated Standards for Reporting Trials
ddc	Zalcitabine
ddI	Didanosine
d4T	Stavudine
EQ-5D	EuroQol 5-Dimensional outcome questionnaire
HCP	Health care professional
HIV	Human Immunodeficiency Virus
HIV-SN	HIV–associated distal sensory neuropathy
HLOE	Highest level of education
HSM-SEWS	HIV Symptom Management Self-Efficacy for Women Scale
HRQoL	Health-related quality of life

ICC	Intraclass correlation coefficient
ICF	International Classification of Functioning, Disability and Health
IMMPACT	Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials
LWHA	Living with HIV/AIDS
M	Mean
MOS-SF-36	Medical Outcome Study Short-Form Health Survey
MPQ	McGill Pain Questionnaire
NSAIDs	Nonsteroidal anti-inflammatory drugs
OI	Opportunistic infection
OMERACT	Outcome Measures in Rheumatology
OR Tambo	Oliver Reginald Tambo
PIS	Pain Interference Score
PL	Positive Living
PLWHA	People living with HIV/AIDS
PMI	Pain Management Index
PPTB	Physical performance task battery
PSEQ	Pain Self-Efficacy Questionnaire
PSMP	Positive Self-Management Programme
PSS	Pain Severity Score
QoL	Quality of Life
RA	Research assistant
REALM	Rapid Estimate of Adult Literacy in Medicine
rhNGF	Recombinant human nerve growth factor

SD	Standard deviation
SE-6	Self-Efficacy for Managing Chronic Diseases Six-Item Scale
SILS	Single Item Literacy Screener
SMS	Self-management support
S-TOFHLA	Short Test of Functional Health Literacy in Adults
TOFHLA	Test of Functional Health Literacy in Adults
TR	Therapeutic relationship
USA	United States of America
WBPQ	Wisconsin Brief Pain Questionnaire
VAS	Visual Analogue Scale

Abstract

Background: Pain is the one of the most prevalent symptoms in people living with Human Immunodeficiency Virus/Acquired Immune Disease Syndrome (HIV/AIDS) and is largely undermanaged. In urban amaXhosa women living with HIV/AIDS (LWHA), the 'Positive Living' (PL) programme has been identified as an effective non-pharmacological intervention for managing pain and may be affected by an empathetic therapeutic relationship. As a high prevalence of pain is likely to exist in rural amaXhosa women LWHA in South Africa, research is warranted on these two interventions amongst this population.

Aim: To determine the effect of the combined PL programme and therapeutic relationship intervention (PL intervention), in comparison to a therapeutic relationship intervention (TR intervention) alone on pain severity, pain interference, symptoms of depression, health-related quality of life (HRQoL), self-efficacy and physical function in rural amaXhosa women LWHA.

Method: A single-blind randomised trial was conducted using a sample of convenience. Interviewer administered questionnaires and functional tests at Baseline and at Weeks 4, 8, 12 and 24 were collected for the PL and TR intervention groups. Regression analysis determined the change of the primary outcomes, pain severity and interference, and secondary outcomes over the 24 weeks of the study.

Results: Forty-nine amaXhosa women LWHA participated in the study. The PL programme and the data collection points were poorly attended by both groups. The pain severity and pain interference scores improved significantly in the PL (n = 26) and TR (n = 23) intervention groups over the 24 weeks of the study, with no significant differences between intervention groups. Symptoms of depression, HRQoL, self-efficacy and six of eight physical function tests were also significantly improved in the PL and TR intervention groups and, with the exception of self-efficacy, no significant differences existed between intervention groups.

Conclusion: The therapeutic relationship appears to be sufficient to manage pain in rural amaXhosa women LWHA and should therefore be recognised as a necessary intervention to provide effective and adequate pain management.

1 Chapter One: Introduction

South Africa is home to the largest Human Immunodeficiency Virus/Acquired Immune Disease Syndrome (HIV/AIDS) population internationally[1]. Amongst people living with HIV/AIDS (PLWHA) pain is one of the most prevalent symptoms[2–5], which is also true for PLWHA in the Eastern Cape, South Africa, part of the Sub-Saharan area[6]. The Eastern Cape, where this study was conducted, is largely populated by rural amaXhosa people, among whom the prevalence of pain in PLWHA is unknown. The prevalence of pain in rural amaXhosa women living with HIV/AIDS (LWHA) is unlikely to be vastly different from urban amaXhosa women LWHA, whose prevalence of pain is 74%[7,8].

As HIV/AIDS transforms from being regarded as a terminal illness to a chronic debilitating illness[9], lengthening the life expectancy in PLWHA[10–12], health-related quality of life (HRQoL)[13–15], and poor pain management, have become bigger concerns[9,16,17]. Despite the high prevalence of pain amongst PLWHA, pain is largely undermanaged[2,18–25]. A need exists for effective pain management for amaXhosa women LWHA, given the likelihood of a high prevalence of pain[7,8], which negatively affects physical and psychological functioning and HRQoL[9,16,17], particularly in women[20,26–28].

1.1 South African context of HIV/AIDS

South Africa has an estimated 6.19 million HIV+ people[29], making up the largest proportion of the worldwide HIV+ population of 35 million[1,30]. Life expectancy for PLWHA in South Africa has increased with the introduction of anti-retroviral therapy (ART) into the public health sector in 2004[10–12,30]. AIDS-related deaths in South Africa nearly halved from 380 000 in 2005 to 200 000 in 2013. In South African populations, PLWHA, receiving ART before their CD4 T-cell count drops below 200cell/μl, have near normal life expectancy[12]. Further, a higher baseline CD4 T-cell count prior to ART initiation, longer duration of ART, and being female all increase life expectancy in PLWHA in South Africa[10–12]. Consequently, HIV/AIDS has become viewed as a chronic debilitating disease rather than a terminal one[9].

The number of PLWHA on ART in South Africa, and in the Eastern Cape, has risen dramatically, from 47 500 (95% CI 42 900 – 51 800) in mid-2004 to 1.79 million (95% CI 1.65 - 1.93 million) mid-2011, and 5 300 in mid-2004 to 187 000 in 2011, respectively[10]. The South African National Strategic Plan was largely met as 80% of PLWHA who qualified for ART, using the initial criteria for starting ART, received treatment between 2007 and 2011[10,31].

As a consequence of the successful ART rollout, the prevalence of HIV is rising annually despite the incidence reducing[30], maintaining a high prevalence of HIV/AIDS in South Africa, and in the Eastern Cape[30]. Therefore, improving pain management in PLWHA in South Africa and the Eastern Cape, needs to become a higher priority. As the experience of pain and its management differs between cultures[6,8,32–34], understanding rural amaXhosa women and their cultural and economic context is valuable in developing effective pain management strategies for this population[35–39].

1.2 Research setting

This study is concerned with evaluating the efficacy of pain management interventions and the 'Positive Living' (PL) programme, amongst rural amaXhosa women. The response of rural amaXhosa women may differ from urban amaXhosa women[40–45], for whom the PL programme was found to be feasible and effective[46,47], as biopsychosocial differences exist between these populations[32,33,35–39,48].

The original PL programme, on which this study is based, was researched in an urban low-resource informal settlement outside of Cape Town, in the Western Cape[44,46]. The setting for the present study is Zithulele Hospital and the surrounding clinic areas, which is part of rural Eastern Cape[45,49,50]. Predominantly amaXhosa people live in this part of the rural Eastern Cape[45]. Many differences exist between these urban and rural environments regarding prevalence of HIV/AIDS, culture, terrain, economics, levels of education and health care, which need consideration in the implementation of treatment[40–45,49,51,52].

The prevalence of HIV is higher in the area of the present study than the previous study on the PL programme. In the Oliver Reginald Tambo (OR Tambo) District, which Zithulele Hospital and surround clinic areas are a part of, the prevalence of HIV was between nine and 12 percent in 2012, while the HIV prevalence in the City of Cape Town was between six and nine percent[51].

Zithulele Hospital provides services for 130 000 people in an area of just under 1000 square kilometres, meaning that a patient may have to drive for over 45km of poor quality dirt road in a hilly terrain to reach the district hospital, or walk if the patient does not have finances for transport[49,50]. This journey by car takes about one hour[49]. Only 3 785 people in this area served by Zithulele Hospital were receiving ART in October 2013[53]. There is a paucity of publicly available information regarding the prevalence of HIV/AIDS in this catchment area and how many people may have been untested and untreated at this time.

1.2.1 AmaXhosa culture

The amaXhosa culture is the most prominent within Zithulele and its surrounding areas[45], making it unsurprising that amaXhosa women living in these rural areas are much less influenced by other cultures[40]. In comparison, amaXhosa women living in urban areas are far more influenced by other cultures with whom they live in close proximity and integrate with[40,44,45]. Therefore, amaXhosa people living in rural areas live far more traditionally than those in urban areas[40]. However, although the heads of the homestead are traditionally men, migration of men to the urban areas has meant that women commonly perform this role within a family[42,43].

AmaXhosa women commonly live a transient life, visiting their husbands in urban areas or searching for work opportunities themselves[40]. As unemployment is a reality for many who live in Zithulele and its surrounding areas[45], financial provision for many rural amaXhosa families is from family grants or pensions, and subsistence farming of crops and livestock[43,45].

In Zithulele and its surrounding areas, access to water and electricity is poor[45] and women are required to walk to rivers to fetch water[43]. Further, subsistence farming is common for amaXhosa people, which requires manual work[45]. This context is therefore disabling for rural women LWHA, for whom decreased physical function is a common experience[24,54], as physical functioning is essential for survival and participation in daily community life[43].

1.2.2 Health care services

Public health-services are poorly managed in the Eastern Cape according to the Eastern Cape Health Action Crisis Coalition, the Treatment Action Campaign and SECTION27 organisations[55,56]. Reports on the Eastern Cape highlight a lack of planning, infrastructure and maintenance[55,56]. There are often stock-outs[a] or shortages of medicine for HIV treatment and staff shortages are a reality[53,55,57]. This is the system in which Zithulele Hospital and its surrounding clinics provide health care. However, in spite of this, the Zithulele ART programme is well-managed[53]. That PLWHA on the Zithulele ART programme, which serves the hospital and surrounding clinics, always receive a full regimen of ART at each follow-up is a testimony to the well-managed service[53].

Access to health care for rural amaXhosa women accessing ART at Zithulele Hospital or the surrounding clinics, is reduced by limited transport and lack of finances. The distances between homesteads and clinics or the hospital, and the hilly terrain creates difficulties for viable transport options[58,59], further the finances for transport are costly in relation to an average monthly income, particularly if there is poor food security[6,43,45,57].

As pain is a biopsychosocial construct[32,33,37,48], this specific context of rural amaXhosa women in OR Tambo, Eastern Cape, has potential to influence pain and its management in this cohort. Further, with the existent health care challenges, pain management interventions need to be feasible and sustainable.

[a] An event where a particular medication is exhausted or out of stock at any health care facility at the time of it being necessary for treatment of a patient.

1.3 A theoretical framework of pain – the biopsychosocial model

Pain is a biopsychosocial experience[35–39], within which numerous factors interact[32,33,37,48,60]. Initially, the biomedical model of pain was widely accepted. In this model, the body is regarded as a machine, which could be fixed by addressing biological problems or tissue damage. The biomedical model neglects the role of the mind and brain in altering the pain experience, establishing a mind-body split, and explaining variance in pain by the extent of biological damage or pathology[61]. However, consistently the pain experience does not match the extent of damage[62]. By not recognising the processes of the brain and psychological, sociocultural and behavioural factors as contributors to pain, this model had limitations[60,61].

In response to these limitations and current knowledge, the biopsychosocial model is widely accepted as the most heuristic model to explain pain. Various models of pain have been developed under the biopsychosocial model of pain due to improved understanding of the pain experience and the involvement of the brain[60,63]. One example is the gate control theory of pain[64]. The theory described the influence of the peripheral nerve function and central processes, pattern recognition on the experience of pain, highlighted cognitive and emotional involvement in modulating the pain experience and indicated that pain was not proportionate to tissue damage[64].

A second example is Melzack's pain neuromatrix, which recognises that pain can occur without a noxious stimulus[65]. The neuromatrix model of pain views pain as a higher order somatosensory construct, which is multidimensional and produced by a widely distributed neural network. The evaluative, affective and sensory dimensions of pain are each affected by multiple determinants and together affect pain perception and behaviour[65,66].

Pain is now understood to be complex, and is described by the International Association for the Study of Pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage"[67]. In this description, pain is recognised to be associated with actual or potential damage but not caused directly by it[63,67]. Although noxious stimuli may contribute towards pain, it is modulated by many factors[65].

The central role of the brain, and biological and psychological factors have been focused on in many models of pain. Cognitive involvement, such as fear-avoidance and catastrophising, which hinders pain reduction, have been recognised[60,68,69]. However, social factors, although acknowledged, initially did not receive as much attention. Social factors are highlighted more clearly in the social communications model of pain[70], which highlights the effect of varied social interactions on pain perception and pain expression[71]. Behavioural changes allow observers to recognise an individual's painful experience during social interaction[63]. Additionally, the observers response to pain expressions brings about a vicarious effect and adaptation to noxious responses, which may be moderated by empathy towards another individual in pain[71]. Social factors, therefore, have differing effects on pain experience and vice versa[63,71].

Consequently, effective pain management necessitates a broad assessment of biological, psychological and social factors, to comprehensively understand contributors to, and causes of, pain[48,61]. Furthermore, as a result of the biopsychosocial nature of pain, pain is inter-related with various elements of health, including depression, HRQoL, self-efficacy and function, which are necessary to assess in the presence of pain[2,4,6,9,16,17,38,41,60,72–79].

Establishing effective pain management, based on the biopsychosocial model of pain[32,33,35–39,48,60], is necessary to address the burden of pain amongst PLWHA[2,21,22,25,80].

1.4 Aim and Objectives

1.4.1 Aim of the study

To determine the effect of the PL programme and therapeutic relationship (TR) combined intervention (PL intervention), in comparison to a therapeutic relationship intervention (TR intervention) on primary outcomes, pain severity and pain interference, and secondary outcomes, symptoms of depression, HRQoL, self-efficacy and physical function, in rural amaXhosa women LWHA.

1.4.2 Objectives of the study

In rural amaXhosa women LWHA, to determine the effectiveness of the PL intervention, in comparison with a TR intervention, with regards to:

Primary objectives:

- Pain severity, measured by the Brief Pain Inventory-Xhosa (BPI-Xhosa).
- Pain interference, measured by the BPI-Xhosa.

Secondary objectives:

- Symptoms of depression, measured by the Beck Depression Inventory-Xhosa (BDI-Xhosa).
- HRQoL, measured by the EuroQol 5-Dimensional outcome questionnaire-Xhosa (EQ-5D-Xhosa).
- Self-efficacy, measured by the Self-efficacy for Managing Chronic Disease 6-Item Scale (SE-6-Xhosa).
- Physical function, measured by the physical performance task battery (PPTB).

To determine the aim and objectives, the next chapter will further introduce literature on psychosocial differences between cultures and its impact on the pain experience, the impact of pain experiences of PLWHA and the available management thereof. The literature review includes evaluation of outcome measurement choice. The third chapter explains how the trial comparing the efficacy of the PL programme combined with the therapeutic relationship, to the therapeutic relationship alone, was conducted and provides a detailed description of the two interventions (the PL programme and the therapeutic relationship). The results are presented in Chapter Four for the study sample (both intervention groups), the PL intervention group and the therapeutic relationship intervention group respectively. Here, results on the sample, demographics, clinical characteristics and the objectives of the study are presented. A qualitative aspect is thereafter presented, by means of post-study structured interviews. The discussion follows in Chapter Five, which discusses the results in relation to the objectives of the study. Finally, the conclusion is presented in Chapter Six.

2 Chapter Two: Literature Review

2.1 Introduction

The literature review introduces the psychosocial variables which contribute to pain. It then explores the prevalence, causes, characteristics of pain in PLWHA and discusses the influences of biomedical contributors and psychosocial factors on pain. The management of pain in PLWHA, using pharmacological and non-pharmacological interventions and their benefits and limitations, are then discussed. Lastly, outcome measures appropriate for use in research on interventions for pain in PLWHA will be discussed.

The literature for this review was built from searches in the following databases: Pubmed, Pubmed Central and EBSCO search engines: Africa-Wide Information, CINAHL, ERIC, General Science Abstracts, Health Source, Medline, PsychARTICLES, PsychINFO and SocINDEX. Relevant literature was identified using these key words: Human Immunodeficiency Virus/Acquired Immune Disease Syndrome (HIV/AIDS), pain, health-related quality of life, self-efficacy, depression, function, biopsychosocial, South Africa, amaXhosa culture, self-management programs, exercise. Still further appropriate information was sourced via relevant websites, including StatsSA. The literature was limited to English literature only.

2.2 Psychosocial variables contributing to Pain

As Chapter 1.3 (p.6) describes, pain is an individual biopsychosocial experience[35–39,60,63,65]. Therefore psychosocial constructs which differ between the urban and rural amaXhosa population, such as culture, gender, level of education and health literacy may affect the experience of pain[18,20,27].

2.2.1 Influence of cultural factors on pain

Pain intensity, tolerance and threshold can be influenced by culture and race. The influence of culture and race on pain has been researched in the United States of America (USA) primarily, and between European and Asian cultures[32,33,54,81,82]. Further, a disparity in pain intensity and pain interference in PLWHA has been reported between cohorts from sub-Saharan Africa and the USA[8,22,54]. In a systematic review by Parker and colleagues[24] on pain in PLWHA, pain interference was reported in six cohorts, of which the two South African cohorts reported minimal pain interference while the four from the USA reported moderate pain interference. The lowest pain interference was reported by a South African cohort with moderate pain intensity whilst the highest pain interference was experienced in a cohort from the USA with only mild pain intensity[8,24,54].

This systematic review by Parker and colleagues[24] will be frequently reported from in this literature review, as it is the highest quality of evidence and there are no other systematic review reports on the subject of pain in PLWHA. It should be noted that results of the systematic review poorly represent women due to less female subjects in articles relating to the subject at the time of the systematic review[24]. This systematic review was well conducted and included 28 studies, which were carefully selected for review from 61 studies which met inclusion criteria. Relevant inclusion of studies of a good quality for the systematic review was ensured by the use of a critical appraisal tool. Of the studies, which met inclusion criteria, studies scoring greater than or equal to the mean score, determined by the critical appraisal tool (68%), were reviewed. The 28 studies in the final review each scored above 70%, which is the minimum percentage suggested by Louw and colleagues[83] to represent good quality prevalence studies[84–86]. The review was restricted to English only, possibly excluding other relevant data from studies done in other languages[24]. Additionally, as a result of the use of an electronic database search and not using papers which were unpublished, the author commented that publication bias may be present[24]. Bias may also have been created by the method of one reviewer doing the study appraisal[24].

In literature, South African and black people have repeatedly been described as having stoic behaviour despite experiencing moderate or severe pain intensity[8,22,24,54]. This may result from the need to maintain function for survival in the South African context[43] as the South African cohorts in the systematic review were predominantly poor, had high levels of unemployment with over half receiving no income, and had low levels of education[8]. Both South African cohorts in the systematic review by Parker and colleagues[24] had poor pain management[8], according to the Pain Management Index (PMI), which determines whether pain management is adequate or not by measuring pain severity against the pain medication prescribed[87,88]. However, of participants in the South African cohorts who received pain medication, a higher percentage than expected, of about 50% pain relief, was experienced[8].

Within South Africa, in a study by Mphahlele, Mitchell and Kamerman[8], amongst ambulant and predominantly female black PLWHA, the prevalence of pain at the time of the interview was significantly higher in rural participants compared with urban participants. The difference in prevalence of pain indicates that within South Africa, different sub-cultures, may also contribute to pain prevalence. The rural participants were more impoverished with lower education levels than the urban participants. Both poverty and lower levels of education are risk factors of HIV-related pain, which may have contributed to a higher prevalence of pain in the rural participants compared with the urban participants[8,81,89]. Despite this, at the time of diagnosis, the rural participants had a lower pain prevalence and fewer attended a clinic or hospital due to pain. Authors suggested that this may have been influenced by longer travelling distances to the clinic in rural areas and recall bias[8].

Further differences were found as risk factors for the presence of pain between rural and urban participants in the study by Mphahlele, Mitchell and Kamerman[8]. In the rural cohort increasing age and higher CD4 T-cell counts increased the risk of pain presence, and being on ART and increasing level of education lowered the risk of pain presence. However, in the urban cohort being female and acquiring a tertiary education increased the risk of pain presence and the effect of increasing age was smaller than in the rural cohort[8].

The study by Mphahlele, Mitchell and Kamerman[8] appears to be well conducted, with a moderately large sample. The study makes a useful comparison between urban and rural South African cohorts, indicating that differences in the experience of pain may exist between localities. One limitation of the study may be that the rural cohort only represents one sub-culture of rural South Africa, the Vatsonga people.

Apart from the study by Mphahlele, Mitchell and Kamerman[8] , a dearth of research is available which compares people from South African rural and urban environments regarding pain. Further, the amaXhosa people are not represented in the available research, except indirectly through the rural Vatsonga people, with whom the amaXhosa people share the Nguni culture[34]. Although similarities may exist due to the cultural link, the results cannot be applied directly from rural Vatsonga people to rural amaXhosa women[34].

In addition to a disparity in pain severity and pain interference between cultures in general, the perceived need for pain management differs between cultures, influenced by the hierarchy of other needs[5]. In a Rwandan cohort of PLWHA, only 43% of participants recognised pain management as a need, despite a high prevalence of pain (72%) and 75% of participants with pain receiving inadequate pain management. Access to ART, financial assistance, home-based care and nutritional support, were perceived to be greater needs than pain management, implying a choice to endure pain in light of more pressing needs[5].

Although all of the literature explored in this section does not directly apply to rural or urban amaXhosa people, it shows that people in different cultures and localities may experience pain differently[6,8,34]. Additionally, other social factors such as gender[90–93], levels of education[18,27], and health-literacy[94–96] influence pain and its management.

2.2.2 Influence of gender, levels of education, health literacy on pain

Generally, literature on gender and pain syndromes indicate that women experience pain differently to men due to biological differences[90–93]. A difference in sex hormones affects the prevalence of pain and intensity of pain experience in men and women[93]. Therefore, women might respond differently to men, if given the same pain management, which provides an indication for researching pain management according to gender.

Lower levels of education are associated with higher pain prevalence in cohorts of PLWHA[18,27]. Access to education in urban environments is greater than rural environments[44,45]. Despite a lack of research comparing education specifically of amaXhosa learners in urban areas to that in rural areas, the percentage of learners enrolled in schools and completing levels at each stage of schooling is known to be less in predominantly rural areas, such as in the areas around Zithulele, than those in urban areas, such as the City of Cape Town[41,44,45]. With marked differences between rural and urban education levels, the prevalence of pain in rural areas is likely to be higher than in urban areas.

Health literacy, which is the ability to seek, understand and use health care and information and is contributed to by education, plays a role in pain and its management, and changes the effect of self-management interventions on outcomes[94–96]. A well conducted study by Sperber and colleagues[94], with a large sample size, indicated that participation in a self-management intervention was more effective and improved pain and mobility more in people with low health literacy, who were unable to read health-related words, than those with high health literacy. The results of the study by Sperber and colleagues[94] were from a randomised control trial but are limited because the study sample included only veterans from the USA who were living with osteoarthritis, reducing the generalisability to other cohorts. With low levels of education in the area around Zithulele[45], health literacy may also be low amongst the amaXhosa women included in the present study[97]. If this is found, and the results from Sperber and colleagues[94] are an indication of a general response of people living with chronic diseases to self-management interventions, then the present study should be more effective than cohorts with a higher health literacy.

An individual's lack of ability to act on positive health behaviours is an important contributor towards chronic pain[96]. A study by Briggs and colleagues[96], which studied people with chronic lower back pain found that health literacy (determined by the Short-form Test of Functional Health Literacy in Adults (S-TOFHLA)), as well as pain intensity, were not correlated to outcomes of disability. Using mixed methods in the study by Briggs and colleagues[96], provided greater depth to the study by including interviews, which determined that back pain-related beliefs and fear avoidance behaviour are associated with disability in the presence of chronic lower back pain[96]. The study had a moderately large sample size and was represented by low and high functioning people living with chronic lower back pain. However, the range of socio-economic status of participants may have reduced the variability in health literacy, as every participant scored well for health-literacy. Varied health-literacy between participants would have helped to determine a better reflection of whether differences in health-literacy has on pain and its impact. Further, being an Australian study limits the relevance of these results in varied settings[96].

2.2.3 Sociocultural factors and HRQoL

Literature indicates that sociocultural factors affect pain and other health outcomes, such as HRQoL, differently, which implies that it is relevant to investigate the effect of these sociocultural factors across different groups of people[41,98,99]. However, a paucity of research on sociocultural factors affecting pain and HRQoL in rural and urban amaXhosa PLWHA exists.

In a large cohort population-based study by Jelsma and colleagues[41], rural amaXhosa people living with disability (PWD) compared to urban amaXhosa PWD with the same functional limitation had a reduced HRQoL on multiple regression analysis[41]. Pain and mobility scores, which differed between rural and urban amaXhosa PWD, had the biggest influence on HRQoL[41]. Despite the limitation of using convenience sampling, reducing generalisability, the study was well conducted[41].

In a large sample of 1159 urban South African participants, which was culturally, ethnically and economically diverse, the EQ-5D Visual Analogue Scale (VAS) score, a measure of a participant's present state of health, was significantly affected by many factors[98]. These factors included age, presence of disability, low income, unemployment and each EQ-5D domain (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression)[98]. As people living in the areas around Zithulele have low income and employment, a lower HRQoL VAS score may therefore be expected[44,45,98]. It is important to be aware that although the study was well-conducted, the results may have been subject to a non-response bias as over 50% of the households in the sample population were not interviewed as they were not home at the time of the data collection[98].

Two studies described differences in responses to pain (a domain of HRQoL), between cultures[34,41]. In contrast and surprisingly, no correlation was found between ethnicity and gender, and HRQoL (measured by the EQ-5D VAS) in the study by Jelsma and Ferguson[98]. Therefore, it is relevant to investigate the effect of different cultures and environments on HRQoL and pain as differences in culture depending on environment may or may not affect pain and HRQoL[34,41,98].

The stoic behaviour in people in sub-Saharan Africa appears to influence quality of life (QoL), in addition to pain. A study by Phaladze and colleagues[99], with a large convenience sample (743 participants), determined that a relatively high QoL score of three and a half (on a scale of 1-5, where five represents the highest QoL) was reported by a sub-Saharan cohort of PLWHA, taking into account the numerous symptoms (an average of 17.58 symptoms) and low functioning of the participants. Further, in this cohort 60% had an AIDS diagnosis and a third had a co-morbidity[99]. The outcome measures were reliable and validated for use amongst PLWHA but were not empirically validated or reliable for the settings or the language in which each was used, which may have caused error in the results, although they were deemed adequate and to have content validity by the authors and researchers[99].

Pain and HRQoL, are also inter-related[9,16,17], and both are influenced by sociocultural factors[41,98,99]. Various sociocultural influences must therefore be taken into account to better understand pain in PLWHA and the management thereof, as the prevalence, causes and characteristics of pain in PLWHA as well as the contributors to pain are likely to be influenced by sociocultural factors[8,22,54,60].

2.3 Pain in PLWHA

2.3.1 Prevalence of pain in People Living with HIV/AIDS

Pain is one of the most prevalent symptoms in PLWHA[2–4]. In two cohorts of PLWHA[2,5] pain was the most common symptom reported. Further, pain, causing enough concern to cause health care seeking behaviour, was the first reported symptom, at the time of diagnosis, in over 60% of a cohort of PLWHA in a study by Namisango and colleagues[25]. The study by Namisango and colleagues[25] was generally well conducted and representative of both urban and rural PLWHA in Uganda. Other well conducted studies with large samples, which were inclusive of diverse areas (including rural and urban areas) in Southern Africa, and the Eastern Cape specifically, also report that pain is one of the most prevalent and concerning physical and psychological symptoms of HIV/AIDS[2,6,100]. A limitation in one of the other studies in agreement with pain being the most prevalent symptom, despite using a well validated outcome measure and establishing content validity of translated versions, was not conducting forward and back translation to ensure semantics and not validating the outcome measure in Africa. Although, the outcome measure had been used before in populations of PLWHA in Africa[2].

A recent systematic review on pain in PLWHA by Parker and colleagues[24] (described earlier in Chapter 2.2.1; p.11), with articles published between March 1982 and March 2012, found 24 samples from 28 articles representing 6814 PLWHA[24]. This systematic review showed that the prevalence of pain, which was 54% at point prevalence and 83% over a three-month recall period, has not decreased in the past 30 years. Thus, the prevalence of pain has been a consistent problem despite the introduction of ART[10,31].

Within the range of prevalence rates reported in the systematic review, was a one week (55%), two week (58%), one month (68%), and six month (72%) recall period[24]. In contrast to these prevalence rates, one article, with a sample from Nigeria of PLWHA, reported a much lower prevalence of 27.8%, for a two-week recall period. This prevalence is far below the mean of the other four studies which reported a two week recall prevalence[16–18,27,101–103]. However, the prevalence reported in this cohort is open to bias. This study by Wahab and Salami[101], a descriptive cross-sectional study, received one of the lowest scores (73%) in the methodological appraisal of the study, as the sample did not represent the entire target population, was not described in terms of ethnicity or ART status, and there was no response rate or non-responders noted[24,101]. Furthermore, the number of participants was 79, much lower compared to the other samples[24,101]. Further, the inter-rater reliability was questionable, given the semi-structured interview, by which the prevalence was determined, was done by a number of medical professions[101]. To understand the low prevalence, and mild pain intensity reported in 70% of those who experienced pain, the authors questioned whether pain was thought, amongst the participants, to be a symptom accepted as part of LWHA, to be quietly endured, and not necessary to make complaint of[101].

Another study, published after the systematic review by Parker and colleagues[24] and done in the United Kingdom, with 859 participants, found a point prevalence of pain of 63% of participants at the time of interview[104]. This prevalence of pain falls within the range of prevalence of pain found in the systematic review[24]. The sample was poorly represented by women (less than ten percent were female participants). This was in keeping with the systematic review, in which most papers were from outside of Africa and mostly had poor female representation[24,104]. Conversely, men were mostly poorly represented in the papers from Africa in the systematic review relatively speaking, while women were well represented[24].

In a study in the USA determining the prevalence of joint pain, 50% of participants with HIV/AIDS only and 56% of participants with HIV/AIDS and Hepatitis C coinfection experienced joint pain respectively. The prevalence of joint pain alone amongst this cohort was high, without factoring in other types of pain[105].

Returning to the pooled prevalence of pain, the systematic review by Parker and colleagues[24] indicated that pain in PLWHA is a consistent problem[24]. These results predominantly came from urban areas and the systematic review identified a lack of data from rural settings internationally, limiting the generalisability of the results[24]. A further limitation is that a low percentage, just under a third of the articles included in the systematic review[24] were from lower income countries[4,8,9,17,18,24,72,101,106,107]. Five of these were South African, two of which shared a data set[72,106]. As noted earlier in Chapter 2.2.1 (p.11), only one article reflected an urban and rural environment, but the Vatsonga was the only ethnicity represented in the rural sample[4,8,17,72,106]. None of the South Africa studies had nationally representative samples[24]. This systematic review shows that despite the large burden of HIV/AIDS in South Africa, there is a dearth of literature on specific populations in South Africa[1,24].

There is a dearth of research on pain prevalence amongst amaXhosa populations. The literature available reports the prevalence of pain for ambulant urban amaXhosa women LWHA to be 74% for a one week recall period[7]. No comparative studies on the prevalence of pain in PLWHA have been done in other urban amaXhosa societies or amongst rural amaXhosa populations. In the only article in the systematic review to compare ambulant and predominantly Black African women from rural and urban settings, Mphahlele, Mitchell and Kamerman[8], reported the prevalence of present pain as greater in the rural sample (72%) compared to the urban sample (56%). Rural amaXhosa women may therefore also have a greater prevalence of pain to their urban counterparts[8,34].

Despite the paucity of literature specific to women and rural localities in South Africa, specifically rural amaXhosa people, the current literature suggests that the prevalence of pain is higher in women and people living in poorer communities[73,74,108–110] and higher in rural compared to urban cohorts[8]. Therefore, the prevalence of pain in rural amaXhosa people is likely to be higher than the 74% prevalence found in an urban cohort of amaXhosa women[24].

2.3.2 Causes of pain in HIV/AIDS

HIV-associated pain is multi-factorial, and can be neuropathic and/or nociceptive in nature[19,20], varying in type and cause[24]. This is due to multiple possible causes of pain including the direct effect of the HI virus itself on the central or peripheral nervous system, opportunistic infections secondary to immunosuppression, and ART side-effects[2,8,18,20,25,54,111–113]. Headaches, pain in the gastrointestinal tract, neuropathic pain, musculoskeletal pain and gynaecological pain are common types of pain experienced by PLWHA[7]. Pain is sometimes idiopathic[28], or unrecognised, as indicated in an Italian sample, where 70% of pain syndromes were not identified during admission to the ward or day-care investigations[112]. Additionally, PLWHA experience pain which is not associated with or as a result of HIV[22].

2.3.3 Characteristics of pain in HIV/AIDS

There are various descriptions given to pain to help health care professionals (HCPs) understand pain, its causes and effects. Two descriptors of pain are its intensity and site.

2.3.3.1 Pain intensity and its impact

Moderate to severe pain intensity is most common amongst PLWHA[24]. An urban amaXhosa female sample had similar pain intensity, with Pain Severity Scores (PSS) of 7.52 for worst pain, 4.65 for average pain, 4.14 for present pain, and 3.93 for least pain[7]. In urban and rural South African cohorts, moderate to severe pain intensity was reported by around 60% of participants[8]. In a more recent study in urban South Africa, with women making up over 80% of the participants, the median pain severity at baseline was 6 on an 11-point scale, also representative of moderate pain in this cohort[114]. The results in another recent study by Lawson and colleagues[104] of participants in the United Kingdom, were similar, yielding results of moderate pain severity, which was higher in women (6 on an 11-point scale) in comparison to men (5 on an 11-point scale).

Pain intensity impacts on pain interference, symptoms of depression, HRQoL and function[4,8,9,16,17,24,54,72–74,78]. The impact of moderate to severe pain intensity differed between cohorts in South Africa and the USA, where minimal and moderate pain interference was reported respectively[8,24,54]. In PLWHA in the USA, a significant positive relationship between pain intensity and severity of depression was found[16,73,74]. As an association between pain and psychological symptoms exist, it is unsurprising that with the high prevalence of pain in PLWHA, psychological symptoms are prevalent too[6,73,74,108,115].

2.3.3.2 Sites of pain

In the aforementioned systematic review by Parker and colleagues[24] on pain in PLWHA, anatomical sites of pain were reported in half of the 28 studies included and the number of sites of pain reported ranged between a median of 1, in a rural South African cohort, to a mean of 2.5 sites, in a cohort from the USA. A more recent study by Lawson and colleagues[104] found that the median number of pain sites was 2, which falls inside the range found in the systematic review[24].

In South African cohorts it is common for PLWHA to experience multiple sites of pain[8,116]. The rural cohort in the South African study by Mphahlele and colleagues[8] had a smaller percentage of participants with multiple sites of pain (46%) in comparison to the percentage of urban participants with multiple sites of pain (61%).

In the South African study by Mphahlele and colleagues[8], the abdomen (rural: 30%; urban: 20%), chest (rural: 26%; urban: 30%) and head (rural: 19%; urban: 39%) were in the four most common sites of pain for both the rural and urban cohorts. The fourth site included in the most common sites differed between the rural and urban cohorts. In the rural cohort the genitals (19%) were common, whereas in the urban cohort the feet (33%) were common[8]. Another South African study by Hitchcock and colleagues[17] reported that of PLWHA and neuropathic pain, 84% had pain in their lower limbs. The lower limbs was a commonly reported site of pain for PLWHA in the systematic review by Parker and colleagues[24], and was reported by each study which reported sites of pain. This is unsurprising given that HIV–associated distal sensory neuropathy (HIV-SN) is a common cause of HIV-associated neuropathic pain[17]. Another frequently mentioned pain site in the systematic review was the head[24].

Where more than one site of pain occurs simultaneously, in an individual, as is commonly the case in HIV/AIDS, it could infer two things[24]. One, that multiple pathological processes are occurring simultaneously, or that the person may be suffering from a central sensitisation disorder, which causes widespread pain due to changes in the nociceptive sensory neuron pathways in the central nervous system, which become more responsive to the normal or subthreshold level of excitatory input[24,67,117,118]. With such a wide variety of sources and influences of pain, it is not surprising that many PLWHA experience pain in multiple anatomical sites and that pain intensity differs between individuals[24]. For this reason, a variety of treatments are used to manage pain in PLWHA as treatment needs to target different causes and influences of pain, including different parts of the nervous system[46,60,117].

2.3.4 Biomedical contributors to pain in HIV/AIDS

This section will further explore the biopsychosocial nature of pain, with regards to biomedical factors affecting pain in PLWHA. The impact of CD4 T-cell count, stage of disease, ART and gender on the experience of pain will be addressed.

2.3.4.1 CD4 T-cell count and stage of disease in HIV/AIDS

The relationship between stage of disease or CD4 T-cell count, and pain prevalence or pain intensity is unclear[24,54,73,82]. Pain is common at all stages of HIV/AIDS. Three studies in the previously cited systematic review by Parker and colleagues[24] found that stage of disease, or CD4 T-cell count did not affect the prevalence of pain[24,54,101,112]. However, another two articles in the systematic review found an increased prevalence of pain with the later stages of disease[9,81]. The association of an advanced stage of disease with a higher prevalence of pain was also found in the recent study Lawson and colleagues[104]. Further, in two more studies, which used regression analysis, the risk of the presence of pain was found to increase as CD4 T-cell count decreased[24,73,82] and one more study found association between the presence of pain and having a history of AIDS defining illness[54].

Higher pain intensity has been associated with a lower CD4 T-cell count in one study by Richardson and colleagues[73]. However, pain intensity in this sample was not associated with a history of AIDS defining illness. The participants in the study by Richardson and colleagues[73] had all previously had a CD4 T-cell count below 200 cells/μl.

As previously noted, the majority of these studies were done in high income countries[54,73,82,104]. Therefore, the results of these studies, on the relationship between stage of disease or CD4 T-cell count, and pain prevalence or pain intensity, should be interpreted with caution considering that the context of the present study differs.

2.3.4.2 ART in HIV/AIDS

The systematic review by Parker and colleagues[24] reported conflicting findings on the relationship between being on ART and the prevalence of pain, as indicated in Table 2-1. A study from the United Kingdom by Lawson and colleagues[104] found, in contrast to the other studies presented in Table 2-1, that being on ART or having previously been on ART was a risk factor for the presence of pain[8,54,106,114]. It is noted that the cohort in Lawson and colleagues[104] was comparatively much healthier based on CD4 T-cell count results than the other cohorts from the studies, which found that ART was associated with reduced presence of pain or prevalence of pain[8,54,114]. The cohorts in other studies had average CD4 T-cell counts of equal or less than 200 cells/μl or over half the participants had a CD4 T-cell count of less or equal to 200 cells/μl. This may imply that for PLWHA with a low CD4 T-cell count, ART may be associated with reduced risk of pain presence and for PLWHA with high CD4 T-cell counts that being on ART increases the risk of pain presence[104]. It should be noted that as pain is contributed to by psychosocial elements, the fear of mortality, which may lessen with the use of ART, may contribute to lowering the risk of pain[65,66]. However, the relationship being ART and pain prevalence is uncertain given the conflicting results[8,24,54,73,104,106,114].

Table 2-1: Associations between ART and the prevalence of pain in PLWHA

Author (year) reference	**Setting**	**Sample size (number)**	**Percentage on ART (%)**	**Regimen**	**CD4 T-cell count (cells/μl)**	**Association between ART and pain**
Mphahlele, Mitchell and Kamerman (2012)[8]	South Africa (rural)	125	53	stavudine or didanosine (d4T or ddl; 95%)	199 (median)	Reduced risk of presence of pain with ART.
Mphahlele, Mitchell and Kamerman (2012)[8]	South Africa (urban)	396	68	stavudine or didanosine (d4T or ddl; 91%)	200 (median)	No difference in the risk of the presence of pain with or without ART.
Breitbart and colleagues (1996)[54]	United States of America (All participants had an AIDS diagnosis defined by 1993 Centers for Disease Control HIV classification as CD4+ <200 or clinical category C)	438	54	zidovudine (AZT; n = 122, 28%), didanosine (ddl; n = 43, 9.9%), zalcitabine (ddC; n = 11, 2.5%), and other or multiple (n = 59, 13.4%)	150 (median)	Lowered risk of the presence of pain with ART.

Richardson and colleagues (2009)[73]	United States of America (65% had clinical AIDS defined as CD4+ <200 by the 1993 Centers for Disease Control HIV classification)	339	60	Not specified	(58% had a CD4 <200)	No association to the prevalence of pain with ART.
Lawson and colleagues (2016)[104]	United Kingdom	859	77	Not specified	475	Increased risk of pain with ART or previous use of ART.
Jelsma and colleagues (2005)[106]	South Africa (urban Xhosa) (All World Health Organization stage 3 and 4 clinical criteria as a result of a history of or current HIV-related illness, including tuberculosis; CD4 count less than 200/mm3)	117	81 (for the duration of the study)	Not specified	Not recorded	Reduced prevalence over time on ART.
Mphahlele, Kamerman and Mitchell (2015)[114]	South African (urban)	92	65 (on ART at baseline)	Not specified	(53% had a CD4 <200)	Reduced prevalence over time on ART.

This said, ART, especially neurotoxic anti-retrovirals (ARVs) such as stavudine, didanosine, and zalcitabine, are thought to contribute to the development of painful neuropathies[113]. Distal sensory polyneuropathy was correlated to use of ART and previous use of D4T in a South African cohort[119]. Further, pain, aching and burning are the most reported symptoms of sensory neuropathies, and are more common than numbness or pins and needles, in stavudine-exposed PLWHA[119,120].

The relationship between ART and prevalence of pain is inconclusive[8,24,54,73,106]. However, this is unsurprising given that there are many different regimens of ART[121] and many factors which influence pain as pain is a biopsychosocial experience[65,66].

2.3.4.3 Gender in HIV/AIDS

Literature shows that women LWHA have a high prevalence of pain[24,54,73,74,109]. In the systematic review by Parker and colleagues[24], a higher prevalence of pain was found in women than men LWHA in three studies[54,74,81]. The two studies in the systematic review of female only samples, reported a prevalence of pain of 63% at a one-month recall and of 83.5% at a six-month recall[24,73,109]. Parker and colleagues[116] found a 74% prevalence of pain in urban amaXhosa women and Mphahlele, Kamerman and Mitchell[114] found an 85% point prevalence of pain at baseline in a sample where 82% of participants were female, however a comparison for prevalence between women and men was not made. In a study by Lawson and colleagues[104] the pain prevalence of women was always higher than the pain prevalence of men over time.

Risk factors for pain differ for men and women LWHA. One study has shown that women are more at risk of new onset distal neuropathic pain than men[122]. Further, certain opportunistic infections are specific to women, such as cervical human papillomavirus infection, candida vaginitis and pelvic inflammatory disease, all of which present with pain[89].

Literature on the differences in pain, not specific to any condition, between genders has indicated that for many pain modalities women are more sensitive to painful stimuli than men[123]. In one study, which evaluated the difference between genders on pain using a cold pressor experiment, showed that women reported higher intensity of pain compared to men[124]. In another experimental study by Sullivan, Tripp and Santor[125] women also reported higher pain intensity than men. In this cohort Sullivan, Tripp and Santor[125] found that fear was a predictor of pain intensity and behaviour for women, and that if pain catastrophising scores were statistically controlled there were no gender differences for pain and pain behaviour. Further there are a number of studies which indicate that females have a higher prevalence of pain for many conditions in comparison to men, including for neuropathic pain and musculoskeletal pain[123]. Therefore, for HIV-related pain may be more prevalent and of higher intensity amongst women in comparison to men. However, the impact of gender specifically on pain in PLWHA remains unclear[24].

From a psychosocial perspective women experience and respond to pain and pain management differently to men too[20,89]. Women have different pain behaviours to men[125] and women LWHA are more commonly undertreated for pain[28]. Further, women LWHA experience depression more commonly than men LWHA, and depression negatively impacts on pain[16,73,74,126,127].

As pain and QoL in PLWHA are inter-related[9,16,17] differences in QoL between genders may influence pain. The study by Sarna and colleagues[128] demonstrates that women LWHA commonly experience concerns over finances, family, loss of relationship and disease progression, which reduces QoL[128] and has the potential to impact on pain[129]. Interestingly, pain was reported more commonly by women in this study compared to men[128]. In considering the results it should be noted that convenience sampling was used and the sample size was small[128]. In another study HRQoL was reported as lower in women than men and pain was one of the biggest contributors to the difference in HRQoL between men and women[129].

This section on the effect of gender differences on pain has indicated that there is also an effect of psychosocial factors on pain in PLWHA[20,28,89,128,129]. The impact of psychosocial factors on pain in PLWHA will be discussed in more detail in the following section.

2.3.5 Psychosocial factors and pain in PLWHA

As a result of the focus of research frequently being on PLWHA from high-income countries and on men, there is less research to inform HCPs on the needs of PLWHA who are women, living in poorer communities, with low levels of education or rural contexts, or of amaXhosa culture[24]. The next section will explore the available research on the contribution of poverty and education on pain in PLWHA.

2.3.5.1 Poverty and pain in PLWHA

Current research indicates that pain prevalence is high in PLWHA living in poorer communities[24,74,108,110]. This was indicated by two samples in the systematic review by Parker and colleagues[24], which focused on people from poorer communities in high-income countries[74,108,110]. Two papers were generated by one study and sample[74,110]. Both of these samples had a very high prevalence of pain in relation to the range of prevalence of pain reported in the systematic review by Parker and colleagues[24,74,108,110].

In one of the samples (296 participants) of poorer communities in the systematic review a 91% prevalence of pain was reported at a one-week recall, using a cross-sectional study design[74,110]. There was a high percentage of substance abuse in the sample and depression was experienced by almost half the sample. The high percentage of depression in this cohort suggests that depression may be more present within poor communities of PLWHA and as depression is associated with pain, pain is likely to be experienced quite commonly in poor communities[74,110]. The second sample (151 participants) in systematic review, which represented people who are from poorer communities and who had an advanced stage HIV or AIDS, the prevalence of pain was 83% over a three-month recall[108]. The basis of the advanced stage HIV or AIDS diagnosis was not included in the study methods. However, the study reported that the most recent CD4 T-cell count for 61% of the participants was equal to or under 200 cells/μl, which indicates the low level of health in the sample. Both were well conducted studies with moderately large samples[74,108,110].

According to one study by Dobalian, Tsao and Duncan[81], unemployment amongst PLWHA in the USA, a high-income country, was associated with higher pain intensity compared to employed participants. Interestingly, over 50% of the sample of PLWHA were unemployed[81]. This was a well conducted study with a sample size of over 2000 PLWHA. Further, according to the study sampling and analytical weighting performed, the results of the study are nationally representative for the USA[81]. However, it is important to note that only PLWHA who received care participated in the study, therefore only representing those with sought out care[81]. In addition, in a study by Parker[7], despite high unemployment percentage in a sample of amaXhosa women LWHA in South Africa (66%), a higher unemployment rate was found in PLWHA reporting pain than those without pain[7]. Parker[7] used a cross-sectional design for the clinical analytical descriptive study, in which amaXhosa women LHWA attending a clinic were interviewed for the presence of pain, using the Brief Pain Inventory (BPI).

In poorer communities, where unemployment is common, such as the community of Zithulele and the surrounding areas [45], a high prevalence of pain and pain intensity in PLWHA, which impacts on function[78], is likely to be found[74,81,108,110].

2.3.5.2 Education and pain in PLWHA

Lower levels of education appear to be associated with higher pain prevalence and intensity in PLWHA, according to the systematic review by Parker and colleagues[24,74,81]. The association between level of education and various factors of pain, namely pain intensity, pain interference, and duration of pain or frequency of episodes, has also been described in other clinical populations, including cancer[130], chronic pain[131] and back pain[132]. With regards to people with cancer and back pain, the evidence is inconclusive although it suggests that an association between pain and level of education exists[130,132].

Cano, Mayo and Ventimiglia[131] found a negative correlation between level of education and pain intensity and interference, where people living with chronic pain with higher levels of education reported lower pain intensity and interference. The sample in the study by Cano, Mayo and Ventimiglia[131], included Caucasian and African American participants. Caucasian participants had a significantly higher level of education compared with the African American participants, and the pain intensity and interference amongst Caucasian participants was lower than that of the African American participants. The pain coping strategies were also different between these two groups. Further, the sample well represented each ethnicity with 62 Caucasian participants and 43 African American participants, and a total sample of hundred and five participants[131].

Juarez, Ferrell and Borneman[130], in a study in the USA suggest that differences in level of education, amongst other factors, influence the pain intensity reported by participants. A large difference in years of education between Hispanic participants (eight years of education) and Caucasian participants (14 years of education) was found, simultaneously with a significantly higher pain intensity in Hispanic participants compared to Caucasian participants[130]. However, no relationship between level of education and pain intensity was established in this study[130]. Further, of interest was the differences in beliefs and knowledge between the two ethnic groups on how to manage pain[130].

Support for the association between lower levels of education and higher pain intensity in PLWHA was found in a South African study by Peltzer and Phaswana-Mafuya[6]. Peltzer and Phaswana-Mafuya[6] found a relationship between lower levels of education and increased pain or symptom intensity in a large sample of 607 PLWHA in the Eastern Cape, of which over half the participants were unemployed[6]. The sample was representative of people living in both urban and rural areas[6]. Convenience sampling was used, which may have caused bias in the results as the participants were found as a result of knowing an interviewer or being identified by key informants. However, the results are in agreement with the previous presented literature[24,74,81].

In contrast, another study in USA by Breitbart and colleagues[54], found no correlation between education and the presence of pain or pain intensity[54]. The study by Breitbart and colleagues[54] did not report on socioeconomic levels, which may be a contributing factor to the relationship between level of education and pain. In other cohorts where poverty and unemployment were predominant, the association between low levels of education and pain appears to be more apparent[6,24,74,81]. In the previous section Chapter 2.3.5.1 (p.30), high prevalence of pain and higher pain intensity has been described in the presence of poverty and unemployment respectively, in two samples from the USA[24,74,81].

In South Africa, lower levels of education are more common in rural contexts[8,45,133]. Therefore, the sample of PLWHA in the present study is likely to have higher pain prevalence and intensity in comparison to the sample of amaXhosa women in the sample from Parker and colleagues[46] mediated by education levels[6,24,74,81]. Despite the contradictory findings of literature on the association between pain and level of education, it would appear that low levels of education are of relevance for PLWHA experiencing pain[6,24,74,81].

So far, the literature review has focused on the prevalence, causes, characteristics and contributing factors of pain in PLWHA. This literature review will continue by exploring the management of pain in PLWHA.

2.4 Management of pain in PLWHA

Despite plenty of literature highlighting the prevalence, severity and interference of pain amongst PLWHA, pain is currently undermanaged in PLWHA, as confirmed by nine studies in the systematic review which measured pain management[24]. Women and people of lower levels of education are amongst the most undermanaged PLWHA[18,20,26,27].

Inadequate pharmacological treatment of pain in PLWHA is high, internationally and in South Africa[24]. Six studies in the systematic review by Parker and colleagues[24], reported that between 66-100% of participants had received inadequate pharmacological treatment of pain[4,8,18,21,24,103,134]. The range of 66-100% of patients receiving poor pain management is the same for PLWHA in South Africa, as the two of the studies by Narasimooloo, Naidoo and Gaede[4] and Mphahlele, Mitchell and Kamerman[8], which represent the lower and upper range of inadequate management in the systematic review, are South African[24].

Narasimooloo, Naidoo and Gaede[4] found that 66% of inpatients in a government district hospital, situated in an urban setting, received inadequate pain management. Inadequate pain management was determined by a PMI score, which was calculated using the BPI and category of prescribed medication for pain. The study was a descriptive analytical study, which used convenience sampling and a sample of 100 participants, most of whom were female. As women experience pain and pain management differently to men[20,24,54,73,74,89,109], the results may be biased because the sample was predominantly female[4]. If a larger cohort of men, more equal to the number of female participants, were included in this study it would have limited this bias.

The study by Mphahlele, Mitchell and Kamerman[8], described in Chapter 2.2.1 (p.11) had a large sample established by convenience sampling, and included outpatients only. In comparison to the inadequate pain management reported in Narasimooloo, Naidoo and Gaede[4] amongst inpatients, pain management for outpatients appears worse according to the results of Mphahlele, Mitchell and Kamerman[8]. Pain management was determined using the PMI in the study by Mphahlele, Mitchell and Kamerman[8]. In Mphahlele, Mitchell and Kamerman[8], only 3% of the urban sample received weak opioids, while none of the rural sample did. In addition, no strong opioids were prescribed in either the urban or rural sample. All of the urban participants with severe pain and the vast majority of urban participants with moderate pain as well as all the rural participants with severe pain and moderate pain received inadequate pain management[8]. The results also indicated that in this study sample the urban sample had a higher percentage of adequate pain management compared with the rural sample but no statistical difference between the groups was evaluated[8].

Another South African study by Mphahlele, Mitchell and Kamerman[114], reported that in the sample of PLWHA no opioids were received by participants in severe pain[114]. The study was well conducted and assessed change in pain and its management over time (six months), using translated African language versions of the Wisconsin Brief Pain Questionnaire (WBPQ) and information on prescribed medication. A sample of convenience was taken of PLWHA attending a public-sector outpatient clinic[114]. At baseline, 95% of participants in pain at the time of the interview received no analgesics (neither nonsteroidal anti-inflammatory drugs (NSAIDS) or paracetamol) and six months later 75% of the participants in pain at the time of the interview. The prevalence of pain in the sample dropped over the six months, however, it does not appear that it was due to the use of pain medication as only one of the participants who no longer experienced pain was prescribed an analgesic[114]. It is evident that pain management with regards to pain medication was poor in this sample. Further, the results indicate that when pain medication were received, only paracetamol, NSAIDS and adjuvants were prescribed[114]. Therefore, if a PMI score had been calculated, it would provide information about the percentage and severity of inadequate pain management with regards to the prescription of pain medication.

A further three studies reported that large percentages of PLWHA were given no treatment for pain. For the three studies, a range of 40-73% of participants received no treatment for pain[9,101,135]. Additionally, despite moderate to severe pain severity, no pain medication was administered in 60% of PLWHA in a cohort from a low-income country (Nigeria)[101]. Although the Nigerian study by Wahab and Salami[101] did have methodological flaws, as discussed earlier in Chapter 2.3.1 (p.18) the lack of pain medication, if accurately recorded, in a cohort with a low prevalence of pain still indicates a major problem with pain management in PLWHA, especially as the prevalence of pain may have been higher than reported.

Apart from pharmacological therapy[22,80,136], existing interventions for managing pain in PLWHA include education[137–140], self-management interventions[141–143], cognitive behavioural therapy (CBT)[144,145], physical exercise[146–149], and a recently developed peer-led exercise and education intervention, the PL programme[46,47]. Literature on these interventions for managing pain with PLWHA follows.

2.4.1 Pharmacological pain therapy

Current evidence indicates limited efficacy of available pharmacological management for pain in PLWHA[22,80]. Partly due to this limited efficacy, a paucity of pain management guidelines and evidence for HIV-related pain, particularly HIV-SN, exist. Furthermore, many challenges such as inadequate knowledge of pain management for PLWHA and in the South African context the irregular availability of medication[2,150–152] reduces the feasibility of using pharmacology alone in managing pain in HIV/AIDS.

Current evidence recommends the World Health Organization's pain ladder guidelines for adults[153] as accepted practice for the management of pain in PLWHA despite these guidelines not being validated amongst the HIV+ population[19,22,27,89,151]. For neuropathic pain, which is commonly experienced in PLWHA[80], the neuropathic pain treatment guidelines for South Africa are recommended[22,80].

Neuropathic pain is difficult to treat[80] for a combination of reasons. It is often not well recognised in the clinic, its management is not well known, and the medication to treat it is limited in terms of both effect and availability[80,150]. For pain management of HIV-SN, a commonly experienced neuropathic pain in PLWHA[17] (Chapter 2.3.3.2; p.23), only high-dose topical capsaicin 8%, smoked cannabis, and recombinant human nerve growth factor (rhNGF) are more effective than placebo[136]. However, regular use of smoked cannabis as therapy is not recommended for legal reasons and for its adverse mental health effects[154], rhNGF is not available for clinical therapy[136] and topical capsaicin 8% is not available in South Africa[80].

Despite the burden of pain amongst PLWHA there is currently no feasible pharmacological intervention which is more effective than placebo available in South Africa[22,80]. Current pharmacological guidelines have recommended the addition of non-pharmacological interventions to adequately manage pain[22,80].

2.4.2 Non-pharmacological pain therapy

2.4.2.1 Education

For people living with chronic diseases, self-management, facilitated by education is recognised as an important skill[137]. Interventions aimed at improving self-management using various forms of education fall under the umbrella term self-management support (SMS). SMS interventions focus on information provision, behaviour change, technical skills and self-efficacy to varying degrees making each different from one another[137]. Written education and didactic learning mostly focus on information provision and technical skills, whereas interventions including goal setting, group education with active participation and exercise focus more on change in behaviour and increasing self-efficacy[137]. A continuum showing the differences in the focus of self-management support (SMS) interventions, as shown on the next page in Figure 2-1, outlines various options in which education may be provided[137].

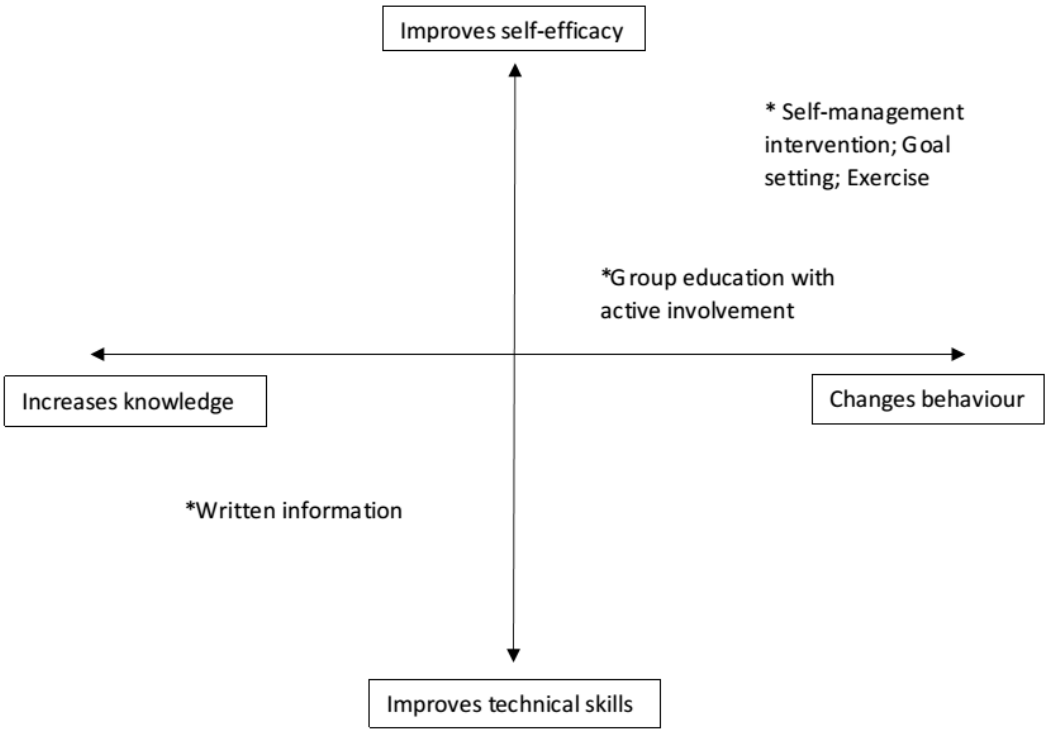

Figure 2-1: A continuum showing the differences in the focus of self-management support interventions

According to the literature review by the Health Foundation[137], interventions for people living with chronic diseases, which focus on self-efficacy and behaviour change, are more beneficial for sustained health outcomes and quality of life[137]. However, the health outcomes were unspecified[137]. One meta-analysis of 17 studies found that the pooled data of SMS interventions had a small effect size for reducing pain in people with arthritis living in the USA[155]. Most of the interventions used were primarily based on the cognitive behavioural theory (n = 4) and/or the social cognitive theory (n = 9). The 17 studies differed in many aspects including the training of the facilitators (therapists, physicians or educators), frequency and duration of the educational sessions, whether education was given to a group or individuals, and the medium in which it was presented (face to face or over audio or video)[155]. It is important to note that with the variety of methods in the 17 studies, the results of the literature review reflected different effect sizes of SMS amongst the studies[155].

It is understood that education by information provision alone may increase knowledge but is unlikely to be sufficient for improving self-efficacy and changing behaviour[137]. Although one study found that participants with acute pain, who were given written information explaining pain and knowledge for self-management, had more behaviour changes than those who received usual care in the short term, there were no significant differences after six-months. Furthermore, the change in behaviour did not translate into improved change in function. Taking into account the limited effects of education on participants' health, the authors recommended that education should be provided along with other therapy[138].

Education by information provision alone appears to have a reduced effect on health outcomes in the long term[139]. For people living with arthritis, a programme which gave participants written information and follow-up information in the months thereafter tailored to personal factors such as demographics, health status and self-efficacy, and a group self-management intervention (a programme designed to facilitate increased self-efficacy and improve self-management) had similar outcomes at two years post intervention baseline. The group self-management intervention was run by two trained leaders, one of whom was a peer-leader and neither of whom was a HCP. By the third year the participants in the self-management intervention had significantly better scores for role function in HRQoL and significantly fewer doctor visits compared to the participants in the intervention giving tailored written information[139]. The tailored written information intervention with follow-up was 12 to 18 months in duration, and the self-management intervention was only six weeks. Therefore, the self-management intervention appears to be a more efficacious intervention than the tailored written information intervention[139].

The above results are further supported by a study on elderly women who experienced pain for over three months[75]. Ersek and colleagues[75] found that fewer pain management skills were reported in those who received an educational booklet compared with those who participated in a self-management intervention. Despite the difference in skills between groups, pain severity reduced significantly in both groups and no significant difference for reduced pain was found between the intervention groups at the three-month follow-up[75]. However, the long-term effects of the interventions and skills acquired on pain severity is unknown. In addition, the sample being of elderly women limits the generalisability of the findings[75].

An educational intervention for PLWHA experiencing pain in Malawi found that education reduced pain more significantly than usual care at eight weeks[140]. However, as the effect of education appears to reduce over time, the effect of the educational intervention may reduce in effect in the long term[140]. In this study, the educational intervention group received written information, a 30-minute face to face information session on managing pain, and a brief follow-up telephone conversation, which provided an opportunity for further questions. In contrast, the control group received routine care, with minimal information for pain management[140]. While the reduction in pain is an encouraging results, the improvement in pain at eight weeks in the educational intervention group may be biased by the additional attention received[140]. The development of a therapeutic relationship between the patient and health care provider was not controlled for in the study design introducing a potential source of bias[156–159]. A further study using three groups: usual care; educational intervention and a therapeutic relationship intervention with the additional contact than those in the educational intervention group receive, would control for this variable.

It appears that although education, in the form of didactic passive learning, may improve pain and help facilitate changes in behaviour; the effect in the long term is unclear[138–140]. Further, the long term effect of education in comparison to self-management programmes on pain reduction remains unclear[75,140]. The research suggests that education should be used in conjunction with other forms of SMS to improve pain[138].

2.4.2.2 Self-management interventions

Self-management interventions are more intricate than education alone, and include a combination of SMS interventions in a programme[77,137,160–163]. There appear to be long term effects of self-management interventions on pain and other health outcomes[75,140].

2.4.2.2.1 Theoretical Model

Self-management interventions are based on social cognitive theory, which led to the self-efficacy theory, and CBT[160,164,165]. The focus of self-management interventions is on developing self-management skills, particularly increasing self-efficacy, which facilitates active participation in chronic disease management. Self-efficacy is integral to positively changing thought patterns and behaviours, having an impact on health outcomes[77,160–163]. These self-management skills help regulate or reduce the effects of the chronic disease on health despite changes occurring in the disease process[165].

To achieve self-management, participants need to learn to manage three different areas: medical or behavioural, role, and emotional[165]. Managing medical and behavioural areas includes lifestyle modifications such as adhering to medication, a change of diet, and a change of activities and exercises. The roles people play in work, family and community life often need to change and modifications of one's responsibilities or the technique, duration and frequency of tasks, which one performs to fulfil a role in society, need to be established. As change and living with a chronic disease is commonly met with emotion, learning how to manage various emotions is part of self-management of living with a chronic disease[165]. In addition, self-management is based on five skills: problem solving, decision making, resource utilisation, forming a patient-HCP partnership and taking action. In order for successful self-management to be learnt, the skills the patient trains in must be related to their particular needs and context[165].

In order to change behaviour, individuals need to have more than knowledge that it is beneficial to change. They need to believe that they are able to control and change their behaviour[164]. The social cognitive theory theorises that behaviour, thought, affective and external factors, which inter-relate with each other, also influence functioning of individuals and can be influenced by individuals themselves[160]. Self-efficacy comes as a result of setting and obtaining goals by accomplishing performance tasks and becoming more confident in the ability to set and achieve goals and behaviour differently[166]. Self-efficacy increases as desired behaviour is developed and confidence is found in being able to behave as required in response to situations which arise. Closed groups provide a setting which stimulates change in behaviour and provides support and problem-solving around obstacles[142,165].

Developing self-efficacy is enhanced by performance mastery, modelling, social persuasion and interpretation of symptoms, and physical and affective states[164,165]. Performance mastery is needed to change behaviour and develop confidence and a sense of control in self-management[142,164,165]. Successes are needed to build self-efficacy, and therefore individuals need to overcome obstacles by problem-solving and perseverance. While failures undermine self-efficacy, if individuals learn from failures how to problem-solve and turn it into success, self-efficacy can be enhanced[164].

In self-management interventions, successes and increases in self-efficacy are achieved by contracting, a process of setting and accomplishing action plans towards desirable and attainable goals[142]. This involves problem solving, learning to manage areas of life which can be controlled, and adjusting behaviour and thoughts to improve symptoms and QoL[163,167]. Action plans must be concrete and specific and ones which participants feel confident they can achieve[142].

Successes early on in an intervention are optimal for increasing self-efficacy, however, self-efficacy can be learnt from failures at this stage too. Despite failures in early stages having a larger negative effect on self-efficacy, as confidence in self-ability has not yet been established, participants who fail at action plans continue to problem-solve in a supported group setting until success is achieved, leading to perseverance and stronger self-efficacy[164]. Failure requires review and alteration of action plans to make them more suitable and achievable[165]. The group encourages, gives feedback and supports one another in problem-solving to adapt participant's action plans to ensure future successes[142]. As self-efficacy increases, individuals may find confidence in increasingly difficult tasks and overcoming more obstacles which grow resilient self-efficacy[164].

Modelling by successful self-managers, a peer-leader or group peers, facilitates participants' belief in their capabilities. Peers model successes in health outcomes and assist one another with developing problem-solving[142]. Successes are heard of and observed in a group setting, which improves the efficacy of modelling[164]. As modelling only helps if it is of desired and valued outcomes[164], successes by peer-leaders and group members and the content in workbooks must represent and be relevant for the population for which it is intended[165].

Peer-leaders and group members help provide feedback through social persuasion when participants develop action plans[142,164]. Affirming individuals in their capabilities increases belief in themselves, increases persistence and effort, leading to higher competence and increased self-efficacy[164]. Relatively accurate social persuasion is important to not bring about unnecessary failure. Therefore, affirming individual abilities just beyond their ability is more likely to be effective because it is believable[164]. A closed group and social support have a positive effect on self-efficacy and problem-solving, facilitated by having a confidential space in which cohesion and companionship can form[142,164].

Additionally, self-efficacy is increased by participants' ability to interpret symptoms and physiological and affective states, as individuals use physiological and affective states to help gauge health. If participants improve in physical functioning, manage stress and emotions better, and have more knowledge of common symptoms of chronic diseases or HIV/AIDS, it positively impacts on self-efficacy[164,165]. Symptoms of chronic illnesses commonly negatively influence self-efficacy and allow fear to develop when symptoms, which the sufferer does not recognise or understand, occur. As fear, anxiety and awareness of symptoms can exacerbate symptoms, if participants are trained in skills to recognise and respond to symptoms, symptoms can be managed more appropriately, leading to a greater sense of control, reduced fear and reduced symptoms[142]. Therefore, facilitating better problem-solving, recognition and management of symptoms, stress-management, physical functioning and management of medication are focused on in self-management interventions[142].

These theories provide the basis for the structure and methods of implementation of self-management programmes, which increase self-efficacy, and thereby have a positive effect on health outcomes and pain, mediated by behaviour and thought changes[161,162,167].

2.4.2.2.2 Implementation/Structure

Self-management interventions vary slightly in structure but all are based on the theories explored above. The structure includes a group of between 10-15 people, facilitated by a trained leader for either six or seven consecutive weeks of two-hour or two-and-a-half-hour sessions per week[76,77,141–143]. Components of group sessions include discussion around topics aimed at improving self-management, a form of goal setting and contracting called action planning, and relaxation training[162].

Topics covered frequently in self-management interventions include symptom management, medication, nutrition, stress management, exercise, communicating with family and HCPs and evaluating treatments[76,162,167]. Pain is rarely a topic which is covered but has been included in the Chronic Disease Self-Management Programme (CDSMP) content in some studies[76,143]. The topic of exercise is commonly part of the content of self-management interventions, such as CDSMP, however it is not performed in the group sessions[76,143].

During the presentation of the topic of stress management participants are encouraged to learn ways to manage stress to help create a sense of control. For example this could involve practicing relaxation techniques, in order to be able to use relaxation techniques in different situations, including adverse situations such as whilst experiencing pain[167]. In the topic on exercise, participants are introduced to the concept of a 'downward spiral' and 'upward spiral', which occur when they either do or do not exercise, respectively. The 'downward spiral' leads to inactivity, resulting in weakness and sometimes pain, which leads to further inactivity and weakness as the lack of control over exercise continues. Alternatively, to gain control again, starting new exercise and activities is essential. As participants get stronger from activity they in turn might feel less pain and gain confidence to partake in more new activities and exercise[167].

The workbooks used to guide the process of becoming a successful self-manager, should be developed by HCPs in collaboration with people with the targeted condition to ensure that needs and concerns are addressed[142,165]. Further, a self-management intervention developed specifically for PLWHA should therefore include the topic of pain as a high prevalence of pain in PLWHA exists[2–4].

2.4.2.2.3 Peer-led groups

Peer-led facilitation is appropriate for self-management programs as it appears to have similar outcomes to HCP-led facilitation, and is a cost-effective alternative[76,162]. Self-management interventions for chronic diseases such as arthritis, HIV/AIDS and other chronic diseases, are commonly facilitated in peer-led groups[47,76,77,141,162,168]. To identify a suitable peer-educator for an intervention with PLWHA, consulting local structures in the community, including HCPs working with PLWHA and prominent leaders or members in community is common. After being appropriately selected, peer-leaders engage in training to run groups[47,141], covering curriculum, practicing group facilitation and guiding action plans and receiving constructive feedback[141,142].

Using a peer-leader has been received positively by participants in two studies[57,141]. Participants in these studies expressed that peer-led groups increased group participation and willingness to share experiences. Group participation brought about increased acceptance and identity and equipped people to cope better with LWHA[57,141]. Further, the culture and environment which groups create, has the potential to influence the psychosocial nature of pain[16].

2.4.2.2.4 Efficacy of self-management interventions

Group participation in self-management interventions has been found to significantly reduce pain in people living with chronic disease[76,77,162] and in PLWHA[142,169,170]. Additional benefits of self-management interventions include improvements in depression, QoL and function[76,77,141,162].

Participating in self-management interventions appears to improve self-efficacy, which improve health outcomes[77,142]. In a study by Lorig, Gonzalez and Ritter[77], people with osteoarthritis, participated in a self-management intervention. Differences between self-efficacy scores between baseline and a four-month follow-up predicted improvements in health status, including pain and depression[77]. The results of the study have strength as the study design was a large longitudinal, randomised control study, which assessed changes over a year[77]. As a result, the study determined that earlier changes in self-efficacy can predict changes in pain[77]. The study was published over 15 years ago, which may render the results out of date[77]. Further, the study assessed the effect of a programme for people living with osteoarthritis only, which therefore means that the prediction of improvement in pain from change in self-efficacy may not apply in other clinical populations[77]. Nonetheless, it is a possible that changes in self-efficacy could predict change in pain in other chronic disease populations such as PLWHA participating in a self-management programme, which is supported by the recent study by Parker and colleagues[46]. In the study by Parker and colleagues[46] participants followed a programme tailored for PLWHA, which was partly based on a self-management programme, in which the self-efficacy scores and pain severity and interference significantly improved over time[46]. However, in this study the self-efficacy results did not predict the reduction in pain severity or interference[46].

In qualitative research by Gifford and Sengupta[142], self-efficacy and playing an active role in management were identified as positive outcomes of participating in a self-management intervention developed for PLWHA. The study used purposive sampling in order that the sample represented a range of responses to the intervention and conducted telephonic interviews from which topics were identified and explored[142].

The effects of self-management interventions on pain are unclear. While Ory and colleagues[76] found a significant improvement in pain, when participants from the USA took part in CDSMP (a self-management programme for a range of chronic diseases), Lorig and colleagues[143] found no changes to pain. Both studies used similar methods. The two studies had peer-leaders who had a chronic disease, and for data collection, participants completed self-administered questionnaires[76,143]. However, the content differed between the interventions. Ory and colleagues[76] specifically targeted pain in their intervention content, whereas the intervention in the study by Lorig and colleagues[143] was more generic to chronic disease management. Therefore, it would appear that in order to have an impact on pain, an intervention needs to include pain specific content[76,143].

From the study by Ory and colleagues[76], it appears that self-management interventions such as the CDSMP are better suited to participants who are less severely affected by their condition or whose outcomes improve during participation[76]. Those in the study with very poor health initially, tended to not complete the CDSMP or failed to return for follow-up tests. This suggests that self-management interventions are not feasible or effective for people with poor health at baseline. It is noteworthy that the analysis of results in the study by Ory and colleagues[76] considered the extent of missing data and used mixed methods to produce an unbiased estimate of the effects of the intervention[76].

Similar to the results of Lorig and colleagues from people living with chronic disease[143], no effects on pain were found in men LWHA, who participated in the Positive Self-Management Programme (PSMP), which, despite the prevalence of pain in PLWHA[2–4], also omitted pain specific content[169]. Additionally, the frequency of exercise in men LWHA, who participated in the PSMP (which included exercise as a topic but was not performed in the group), was not significantly different from the control group. However, participants of the PSMP group had significantly better self-efficacy than the control group over time. This study had several limitations, including being restricted to men and following up for three months only, preventing information on the effect of PMSP and self-efficacy in the long term[169].

Other benefits of self-management programmes include significant improvements in QoL in CDSMP[76]. Further, Webel[141] reported that two out of the nine subscales of the HIV/AIDS-targeted Quality of Life outcome measure were significantly better in urban women LWHA in the United States of America, who participated in PSMP compared with those receiving a workbook (not based on PSMP). However, these scales were also significantly different between groups at baseline. Therefore, the results do not necessarily reflect success of the intervention but could simply be a difference between the groups maintained over time[141]. The results may possibly be negatively affected as, participants reported that peer-leaders in this PSMP did not use the workbook effectively, despite training[141].

In people living with chronic diseases and PLWHA, the benefits of self-management interventions on pain and other outcomes are unclear. Therefore, more research is needed to assess its effect across various contexts. Many of these self-management interventions were developed and studied in the USA[76,77,162], including the PSMP for PLWHA[141,142]. The biopsychosocial nature of pain may change the effectiveness of self-management interventions on pain, according to different socio-demographics and chronic disease[35–39] indicating the need for culturally specific studies.

Research into the efficacy of self-management interventions in combination with other pain management strategies is indicated. Self-management has brought about a significant difference in pain in some studies[76,77,162], but there is minimal research for its effect on pain in PLWHA[169]. Furthermore, the effect of self-management interventions and other pain management strategies have not been explored in combination among rural amaXhosa women.

2.4.2.3 Cognitive Behavioural Therapy

Cognitive behavioural therapy (CBT) is another intervention used for PLWHA experiencing chronic pain. Many self-management interventions are based on CBT and therefore there are many similarities between the approaches. For PLWHA experiencing chronic pain, pain management is one of the main focuses of CBT and covers cognitive reinterpretation of pain and learning skills of problem solving, goal setting, exercise, communication with health professionals and relaxation[144,145,170].

When CBT is delivered in a group setting, the group structure and content are similar to those used in self-management groups with some notable differences. Participation in CBT based management interventions involves twelve weeks of 90 minute sessions led by clinical psychologists. Furthermore, the clinical psychologists are available outside of group sessions[144,145] and may facilitate an improvement in pain management by working directly with physicians[145]. One study allowed rolling admissions, therefore allowing for a continuous change in the dynamics of the group compared with a closed group[142,170].

The results of CBT include reduced pain intensity and pain-related impairment even with moderate attendance of group sessions, however no long-term effect after participating in CBT was recorded[144,170]. In one study, improvement in pain anxiety during treatment was found to play a role in helping pain acceptance that improved pain-related impairment[144]. Other results of CBT indicate that participants with higher pain anxiety at baseline showed greater improvements in pain related functional activity[145]. CBT has also been shown to facilitate improvement in depression[144,170], which may also be mediated through increased pain acceptance, which itself is a result of participation in CBT[144].

Despite positive results for pain management in PLWHA and chronic pain, the CBT intervention is possibly less effective than self-management interventions, as CBT management interventions are lengthier and less cost-effective[76,77,144,145,162]. In addition, they are delivered by psychologists specifically trained in the treatment, which increases the resource requirements[144,145] – a consideration for health care in resource constrained settings.

2.4.2.4 Physical exercise

Exercise can have a hypoalgesic effect on pain[171–173]. Further, the presence of pain is associated with reduced self-efficacy, QoL and physical function[6,78,174], all of which can be improved with exercise[146,148,149]. Exercise significantly increases self-efficacy[149] and improves QoL[146]. However, a paucity of evidence exists for the long term effectiveness of exercise on pain in PLWHA[148,175,176].

Exercise was the most common strategy to self-manage pain, reported in qualitative research by ambulatory PLWHA from the USA experiencing chronic pain[177]. The median CD4 T-cell count of the sample was 571 cells/μl, meaning that on average the participants had minimal immunosuppression and were not at high risk of opportunistic infection[178]. Forms of exercise included housework, walking for a set time or doing sets of exercise routines. Participants' reported that exercise helped ease the pain and was helpful in accomplishing goals[177].

Physical exercise is beneficial for treating pain as exercise increases the release of endogenous opioids, such as endorphins, which inhibit pain and increase pain tolerance[173]. A meta-analysis by Naugle, Fillingim and Riley[179], on studies in which pain was experimentally induced, indicated that exercise is able to reduce the perception of pain in healthy populations. Additionally, in populations with chronic pain, on average a positive small effect size was found for pain reduction from aerobic exercise[179]. However, the results indicated that the effect of exercise on pain was more variable amongst people with chronic pain as hyperalgesia was also reported post exercise, although it was less common[179].

For PLWHA, aerobic and resistance exercise, of low to moderate intensity, is a safe and accepted intervention[147,148], commonly used in the management of other chronic diseases[146]. Exercise is beneficial in alleviating HIV-associated symptoms, HIV-related muscle wasting, metabolic and cardiovascular impairments[146,147,180]. During the early stages of HIV, exercise may increase CD4 T-cell count and decrease viral load as well as delay symptom onset and decrease symptom severity[147].

Although exercise is safe for PLWHA[148,149,181,182], PLWHA should be assessed before starting an exercise regime. Various conditions predispose PLWHA to responding differently to exercise, such as having decreased lung function, after pneumocystis pneumonia, or experiencing muscle cramps or cardiac dysrhythmias following diarrhoea or poor nutrient absorption[147]. Exercise routines should take into account the individual's current amount of exercise and activity, stage of disease, HAART regime and side effects[146].

2.4.2.4.1 Exercise-intensity

Exercise-induced hypoalgesia was more effective with a higher intensity of aerobic exercise compared to moderate intensity amongst healthy participants from the USA, in a study by Naugle and colleagues[171], in which 15 females and 12 males participated. Naugle and colleagues[171] studied the impact of exercise on experimentally-induced pain pressure threshold, which was found to increase post aerobic exercise performed at 70% heart rate reserve[171]. Participants completed three sessions of 25 minutes each, which included higher intensity exercise (stationary cycling at 70% heart rate reserve), moderate intensity exercise (stationary cycling at 50% heart rate reserve) or rest. The order of sessions was randomised and before the three sessions commenced a training session took place to familiarise participants with the procedure of experimentally-induced pain testing procedures[171].

Moderate-intensity exercise, the most commonly advised intensity for PLWHA[147], has no known negative effect and has been reported to be helpful in reducing symptoms of HIV infections and improving the immune system. Exercise of moderate intensity is safe for PLWHA with high viral loads as indicated by the immune response[176]. In a cohort of PLWHA, of predominantly deconditioned participants with high viral loads, exercise did not affect viral load in 22 of 25 participants. In three participants, post-acute exercise, transient detectable HIV RNA was found despite having previously undetected HIV RNA[176].

In a study of men who were HIV+ from the USA by Mustafa and colleagues[175], exercise of moderate-intensity slowed progression of HIV to AIDS, bringing about a slower decline or increase in CD4 T-cell count in those who exercised regularly compared with those who did not[175]. Further, a slower progression to AIDS occurred in men who exercised three to four times weekly rather than daily[175]. The sample in the study included 415 men, of whom 156 were HIV+. This study, with four years of follow-up, shows long-term effect but as it was conducted in the late 1980s, prior to HAART, it is possibly outdated[175].

Another two studies, of which the study by Fillipas and colleagues[149] is more recent than the possibly outdated study by Mustafa and colleagues[175], found no effect of exercise on CD4 T-cell count or viral load[149,181]. In the study by Fillipas and colleagues[149], which also only included men, the effect of exercise on CD4 T-cell count and viral load was assessed at six months, which limits evidence for the long-term effect of exercise on these immune markers[149]. The three studies discussed here further validate that moderate-intensity exercise and slowly progressed exercise is safe for PLWHA and does not negatively affect the immune system in men LWHA[149,175,181]. A major limitation to the three studies is that they primarily focus on men. Two of the studies only had male participants[149,175], while the third study had a sample of 60, with 52 males and eight females, and the sample was then equally divided for the study intervention groups[181].

2.4.2.4.2 Aerobic and resistance exercise

Aerobic exercise and resistance exercises are beneficial for reducing pain[171,172]. Additionally, Baiamonte and colleagues[172] found that resistance exercises increase pain tolerance, which was tested by use of a mechanical nociceptive stimulus, however the pain threshold remained unchanged. Resistance exercises were done in a circuit of nine exercises, performed as three sets with 12 repetitions in each by participants who regularly participated in resistance training[172]. A large effect size for the increase in pain tolerance was found between the pre-exercise results compared to one minute post exercise[172]. The effect did not last long as from one minute to five minutes, there was a significant decrease in pain tolerance. The study results are limited though, as the results do not indicate the effects of exercise-induced hypoalgesia in people who do not regularly train[172].

In the study from Fillipas and colleagues[149], PLWHA (over 18 years old) who took part in two 60 minute aerobic and resistance training sessions during a week over six months, had significantly better self-efficacy and cardiovascular fitness and increased HRQoL as compared with the control group[149]. The control group results stayed much the same as baseline, while the participants in the exercise intervention group did considerably better than their baseline[149]. The training programme took place over six months and followed guidelines of starting at 60% of maximal heart rate, using the Borg Relative Perceived Effort Scale[183], and increasing to 75% as improvement occurred. Resistance training was initially at 60% of one repetition maximum, gradually increasing to 80% and were performed in three sets of ten repetitions and breaks were given between sets and exercises[149]. There was good adherence to the exercise program, which was supervised by a physiotherapist, which may have contributed to the effectiveness of the exercise programme. As mentioned previously, the study only included males, limiting application of the results to women and the length of follow-up time limits knowledge of the long-term effect[149].

Similar to Fillipas and colleagues[149], Hand and colleagues[148], found that for PLWHA from the USA (over 18 years old) participating in aerobic and resistance training is safe and improves functional aerobic capacity[148]. As functional aerobic impairment may partly be due to deconditioning, which can result in pain[167], the finding is useful in order to reduce deconditioning by increasing functional aerobic capacity in PLWHA[148,182]. No significant differences between participants on HAART or not on HAART were found[148]. The study was limited by a small sample size and a high drop-out rate. About two-thirds in the exercise group and half in the control group completed the study. Additionally, women were not well represented as very few participated in the study[148]. Hand and colleagues[148] found that women responded as well as men, indicating that both women and men benefit from aerobic and resistance training but the poor representation of women may limit the strength of these findings[148]. The study was well controlled, and excluded individuals who had an opportunistic infection, had previously used or were currently using hormone therapy, was an alcohol or substance abuser, or individuals for whom it was unsafe to exercise. Further, participants were excluded if they were participating in a structured exercise programme before participation in the study. In addition, dropouts were contacted to find out whether any adverse signs or symptoms occurred but none were reported[148].

Therefore, aerobic and resistance exercise should be part of the management of pain in PLWHA, as exercise is safe for PLWHA and brings about exercise-induced hypoalgesia[148,149,171–173,181,182].

2.4.2.5 'Positive Living programme': a multimodal intervention approach

A multimodal 'Positive Living' six-week peer-led exercise and education intervention (PL programme) guided by a 'Positive Living' workbook (PL workbook), was found to be effective and feasible in managing pain in South African urban amaXhosa women LWHA[46]. The educational contents of the PL programme and workbook were developed by Parker and colleagues[47], for specific use by PLWHA. The contents were carefully chosen from evidence-based educational material, developed by experts (researchers in health, doctors, physiotherapists and nurses), on managing living with chronic health conditions, including HIV/AIDS and chronic pain[167,184–186]. The self-efficacy theory and principles from CBT[160] were used to develop the PL programme[47].

The PL programme has similarities with other self-management interventions for people with chronic diseases[76,77,162] but additionally incorporates performing exercise in the sessions, which facilitates core self-management skills acquisition and promotes self-efficacy[47,165]. The exercise routine was designed to maintain various body functions, which may decline in PLWHA, for example cardiovascular fitness[47,149].

The PL workbook is used to guide each peer-led session over six consecutive weeks[47], which is an adequate amount of time to change behaviour[165]. Peer-led sessions facilitate aerobic and strengthening exercise, relevant topic discussions for amaXhosa women LWHA, development of action plans specific to the weekly topic, and relaxation training[47]. The peer-educators in Parker and colleagues were well familiarised with the content of the PL workbook and referred to the manual during groups sessions. It should be noted that the manual was not used as a script[47]. This manner of facilitating is necessary to clarify as participants of a self-management intervention in a study by Webel and colleagues[141], felt that the peer-leader should have been better prepared and should not read directly from the manual. The study by Webel and colleagues[141] used qualitative research to investigate the participants experiences of the intervention.

The workbook is designed to be used by participants as a resource outside of sessions. Examples of exercise and relaxation routines, symptom charts, and space to write goals are included in the workbook[7,46,47]. Symptom charts assist participants in selecting appropriate action to respond to symptoms, thereby improving self-efficacy with the use of the charts[7]. This model of symptom chart, used in the PSMP, was found to be useful by participants[142]. Additionally, the most important information in a workbook chapter is summarised in blocks, similar to other self-management books, to aid an increase in knowledge of self-management[167].

The relaxation routines aim to facilitate relaxation sessions (in the form of autogenic training)[187]. Relaxation techniques aim to assist behavioural change, which reduces pain, improves self-efficacy and helps with other health outcomes[188,189]. Practicing relaxation appears to enhance the physiological response of the parasympathetic system, whilst reducing the sympathetic reaction to the presence of pain[189].

The efficacy of the workbook on health outcomes may be impacted upon by participants' health literacy[190]. Low health literacy is influenced by lower levels of education and rural living[41,191]. The literacy level of workbooks used in programmes needs to be considered within context. For example, the English version of the PL workbook has a Flesch Reading Ease Score of 72/100 and Flesch-Kincaid Grade Level of 7.8. This indicates that the workbook is appropriate for people with seven years of education[7]. For the urban amaXhosa participants of the study of Parker and colleagues[46], the workbook was found to be appropriate and effective in reducing pain. However, an intervention using a workbook only might be impractical in settings where a high percentage of patients have lower levels of education such as Zithulele and the surrounding areas, where half the population either only had some primary schooling (less than seven years of education) or no schooling[45].

Parker and colleagues[46] found that an intervention group, who participated in the PL programme, and a comparison group, who received a PL workbook without group facilitation, both improved significantly in all outcomes over a 16 week follow up period. These outcomes included pain severity, pain interference, symptoms of depression, self-efficacy and HRQoL[46]. In all outcomes no significant difference between groups were found[46]. While this research applies to urban amaXhosa women LWHA[46], it might not extend to their rural counterparts as a consequence of the differences in culture, educational level and socioeconomic factors discussed in Chapter 2.2 (p.10).

A similar multimodal intervention, designed for people with osteoarthritis who were awaiting arthroplasty, was studied in urban South Africa[192]. This study found a moderate to large effect size on pain severity and pain interference in the intervention group in comparison to the control group[192]. The intervention included aspects of a self-management programme and incorporating education and exercise[192]. It appears that interventions of this type reduce pain in various chronic diseases but the extent to which it may benefit South African people in rural contexts is still unknown[46,192].

Parker and colleagues[46], who studied the intervention designed for PLWHA, theorised that the improvement recorded in both intervention groups may have been due to an unintended effect of the study. Arguably an additional intervention[46], a therapeutic relationship was developed by the consistent care, given by an empathetic HCP, at regular follow-ups. As the effect of a therapeutic relationship (TR) was not studied, the role of the TR on pain and health outcomes compared with the PL programme is unknown.

The implication of the study from Parker and colleagues[46] is that patients may just need to be followed up by the same empathetic HCP each time they visit the clinic. It is therefore relevant to consider the role of the therapeutic relationship on pain and health outcomes.

2.4.2.6 Therapeutic relationship

Many studies have established that a therapeutic relationship is essential in optimising health outcomes in patients[156–159]. The therapeutic relationship has its own effect on outcomes and should therefore be regarded with value and attention during interactions between patient and HCPs[193]. Some researchers consider the therapeutic relationship as an essential platform for treatment, which must exist for change in outcomes to become possible[194,195]. However, the direction of the causal effect of the therapeutic relationship has been queried by some, who question if the outcomes may influence the therapeutic relationship[196,197]. Either way, fostering the therapeutic relationship appears to be important[196].

The therapeutic alliance between the patient and clinician, empathy from the clinician to the patient, and the expectations of treatment for the patient and clinician, all influence the therapeutic relationship[156,195]. Each factor interacts with another and has the ability to enhance or weaken the effect of an empathetic therapeutic relationship on outcome goals[156,198].

In this alliance, the character and behaviour of the therapists appear to have more influence on the therapeutic relationship than the patient. The patient's perception of care contributes towards physiological changes, such as a release of endogenous opioids and neurophysiological changes, even in the absence of analgesic medication, as seen in placebo analgesic effects[199–201]. Patients perceive empathy from a HCP if they feel that they have been listened to and heard by their HCP. This is facilitated by HCPs reflecting their understanding back to the patient verbally, while showing compassion, for example with appropriate facial expressions and tone of voice. Health care professionals have an increased ability to show empathy if they can place themselves in the patient's position[202,203]. Further, HCPs' empathy towards the patient increases patients' trust in HCPs, improves compliance with following medical advice and regimens (also found amongst PLWHA) and promotes healthy behaviour, which are all conducive to improved health[204–207].

In a large study of PLWHA in the USA, a positive relationship between a HCP and patient was necessary to improve adherence to medication[206]. The association between better relationships and improved adherence to medication was strengthened further if the patient had self-efficacy in taking medication[206]. This finding was tested across categories such as race, gender and ART regimen by stratified sampling within the large study which found the finding was consistent. The study included people who were heterosexual, homosexual and bisexual and was 74% men. As the sample was over 2000 people, the data analysis is likely to represent both genders and other categories well[206].

Treating patients as individuals and establishing patient-centred care is important to develop a good clinician-patient relationship[198]. Communication, both verbal and non-verbal, is a key aspect of the therapeutic relationship and perception of care. Patients value being listened to, having their stories, opinions and choices heard, understood and believed[198,208–210]. Other interpersonal skills which are valued by patients include being friendly, confident, empathetic, encouraging and respectful[198,211].

Empathy and behaviours from health care professionals which develop a constructive therapeutic relationship can be improved with training and practice[212–214]. Training, which focused on increasing the ability to be empathetic, improved physician's empathy as perceived by patients in one study[215]. This training incorporated understanding emotions from a neurobiological and physiological perspective, practicing recognising emotion in people's behaviour, practicing behaviour which illustrates empathy and care, and self-development skills, such as relaxation and mindfulness[215]. Further, self-reflection, personal resilience and having a balanced healthy life have contributed towards developing empathy and maintaining it[216,217].

The existence of an empathetic, therapeutic relationship in treatment has primarily been found to significantly reduce psychological symptoms but in addition studies have also recorded improvement in physical outcomes as well[156,197,207]. For example, the therapeutic alliance scores was a predictor of reduced pain severity and improved function in people with chronic lower back pain receiving treatment of either exercises or spinal manipulation by physiotherapists in a study by Ferreira and colleagues[218]. This was a retrospective observational study, which was part of a randomised control trial of 182 participants with chronic lower back pain living in Australia[218]. Therapeutic alliance was assessed at second treatment session, while the outcome measures were assessed at baseline and eight weeks of treatment[218]. Treatments were run by experienced physiotherapists and monitored to maintain a high standard of practice to ensure a well conducted study[218]. Although the study was well designed, ending at eight weeks to ensure that the prediction was as accurate as possible, the limitation is therefore that the long term effects of the prediction are unknown[218].

A second study indicating improvements in physical outcomes arising from the therapeutic relationship was conducted by Fuentes and colleagues[219]. This study indicated that if active interferential current therapy was given in the presence of an enhanced therapeutic alliance for participants with chronic lower back pain, the result was a clinically meaningful improvement in pain intensity[219]. Fuentes and colleagues[219] ran a four-group experimental controlled study with 117 participants, which was conducted with groups either receiving a limited or enhanced therapeutic alliance and active or sham interferential current therapy. Despite receiving either an active or sham interferential current therapy, both groups which received an enhanced therapeutic alliance yielded large effect sizes for pain intensity in comparison to the limited therapeutic alliance groups[219]. Pain intensity was assessed subjectively using a numeric rating scale and pain sensitivity (of the muscle) was assessed objectively using pressure pain threshold. Unfortunately, repeated measurements were done directly after the treatment only and therefore the long term effect is unknown[219].

Improvements in patient's health outcomes and change of behaviour appear to be as a response to being observed and cared for[220]. This is described as the Hawthorne effect, a non-specific element of treatment in trials, similar to the therapeutic relationship, which appears to improve outcomes[220–222]. It appears to primarily be the care, trust and attention received as a response to participating in a trial which impacts the outcomes positively[197,221]. Being in a clinical trial also improves researchers' and HCPs' behaviour towards participants, in comparison to routine care given[222]. The same care can therefore be intentionally given in patient's treatment sessions in routine care[212–214], having the same effect as in clinical trials[199–201,204,207].

It is important to establish the extent to which the therapeutic relationship enhances the outcomes of effective treatments[196]. The PL programme by Parker and colleagues[46] was found to be feasible and effective for pain, however the extent of the effect of the therapeutic relationship remains unknown[46]. Therefore, if an intervention to manage pain in PLWHA is researched, the effect of the therapeutic relationship needs to be considered and valid, reliable and appropriate measurement instruments need to be identified to record the efficacy of the interventions appropriately[223].

2.5 Outcome measures

It is recommended that studies evaluating the efficacy of interventions on pain, should use multiple outcome measures, to reflect the multidimensional nature of pain comprehensively, in order that clinically meaningful change in pain and inter-related outcomes are determined[224]. The guidelines developed by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) group recommend that pain studies consider measurement of pain, physical functioning, emotional functioning, participant rating of improvement and satisfaction with treatment, symptoms and adverse effects and participant disposition. Further, recommended outcome measures appropriate for these domains were chosen foremost on appropriateness of content, reliability and validity, responsiveness (an important aspect of validity for detecting change) and feasibility with regards to burden[223].

2.5.1 Pain

In the systematic review by Parker et al.[24] the most commonly used measurement instrument for pain in PLWHA was the Brief Pain Inventory (BPI), followed by the WBPQ and the Italian Pain Questionnaire (Italian version of the McGill Pain Questionnaire (MPQ))[225–227].

Although the MPQ is often used in pain studies, it has limitations as it does not measure pain interference[226] and has low sensitivity to change over time in comparison with other scales, such as a VAS for pain intensity measurement[226,228]. In comparison, the responsivity of the BPI in measuring change of pain over time is a strength of the BPI[229]. The BPI and the WBPQ measure pain intensity and pain interference, using different scoring for pain interference, and recalling pain over a week, and a month, respectively[227,230]. The BPI-Xhosa has been validated for use in amaXhosa women with HIV[116], while the WBPQ has been translated into Xhosa, but due to insufficient participants has not been validated[34]. This suggests that the BPI is an appropriate assessment tool for assessing the efficacy of interventions on PSS and Pain Interference Scores (PIS).

The BPI, originally developed for assessment of pain in people with cancer[227], has been found to be valid and reliable for use in many conditions related to pain, such as with arthritis, lower back pain or chronic pain[229,231]. Pain severity scores are an average of scores on four questions (pain at its worst, least, average and right now) and pain interference scores are determined by an average of scores of seven questions (seven domains of functional interference). Questions are scored by numeric rating scale from 0-10, where lower scores represent less pain severity and pain interference and higher scores represent higher pain severity and pain interference[87,227].

Additionally, the isiXhosa translation, the BPI-Xhosa, has good reproducibility of original semantics and was found valid and reliable, with good internal consistency, for amaXhosa PLWHA in urban areas[116]. The two-factor structure of the BPI-Xhosa, referring to pain intensity and pain interference, was also found in other South African languages for the WBPQ[34,116].

As per the English version, designed for research and endorsed by the IMMPACT guidelines for pain studies[223,224], the BPI-Xhosa is an appropriate outcome measure of prevalence of pain, pain intensity and pain interference[116]. The BPI-Xhosa is therefore the outcome measure of choice for the primary outcomes, pain severity and pain interference, in the present study.

The translation of the term “average” and the use of the scale had been identified as two difficulties of using the BPI-Xhosa[116]. The authors warned that this outcome measure should therefore be used with caution in studies, more so in rural areas where the BPI-Xhosa has not been tested. To account for this, the authors suggested that the BPI be calculated with and without the score for pain on “average” to check that the data has a similar structure[116].

In addition to determining pain severity and pain interference, the BPI is also used to determine the adequacy of pain management, by a measurement called the PMI[87,88,227]. The PMI determines whether pain management is adequate by measuring pain severity against the pain medication prescribed[87,88]. The level of pain severity is categorised into no pain (zero points), mild pain (one point), moderate pain (two points) and severe pain (three points) using the BPI[227]. The categories for pain medication is as follows: no medication (zero points) mild opioids (one point), moderate opioids (two points) and strong opioids (three points)[87,88,153]. To calculate the PMI, the value of the pain severity is subtracted from the value of the strongest pain medication received. If the PMI score has a negative value then the medication was inadequate, while if the score is positive then it represents adequate pain management[87,88].

2.5.2 Symptoms of depression

Two valid and reliable outcome measures frequently used in people with pain[232], to assess symptoms of depression are the Beck Depression Inventory (BDI) and Center for Epidemiological Studies Depression Scale (CES-D)[233,234]. Further, the BDI is recommended by IMMPACT for pain studies[224] as symptoms of depression are inter-related with pain[24,73,74,126]. Both measurement instruments have advantages with regards to validity when assessing people experiencing pain. The BDI has better specificity in comparison to the CES-D, while the CES-D has better sensitivity compared to the BDI[232].

Due to its brevity and simple language, the BDI is easy and quick to administer, and is appropriate for people with low levels of education[224]. The BDI consists of 21 questions, each with four possible responses of which one must be chosen. Each answer corresponds with a score (0 - 3), and the total BDI score is the sum of the 21 scores[234,235]. The highest total score on the BDI is therefore 63, with a higher score indicating greater symptoms of depression[234,235].

The BDI is a useful measure of symptoms of depression, and although it is not used for diagnostic purposes of major depressive disorder[236] it is sufficient for assessing change in symptoms of depression in PLWHA[232,236]. Further, the BDI is a valid measurement outcome to use in populations with chronic pain[232] and has been used in a South African cohort of amaXhosa women experiencing pain[46].

Two revisions have been made to the BDI, the second being the BDI-II[237,238]. The BDI-II is a reliable outcome measure with initial construct validity, which was demonstrated in PLWHA receiving ART in South Africa[236], amongst whom a high prevalence of pain was likely[2–5,24]. An isiXhosa version of the BDI-II was developed, the BDI-Xhosa and has been found to be valid and reliable[238]. It has subsequently been used amongst rural South African amaXhosa people in the Eastern Cape[239] and urban amaXhosa women LWHA[46].

2.5.3 Health-related Quality of Life

Health-related quality of life is commonly affected when people are suffering from pain[9,16,17]. Although many HRQoL measures exist, the Medical Outcome Study Short-Form Health Survey (MOS-SF-36)[240] and the EuroQol instrument (EQ-5D)[241], have both been translated into isiXhosa to measure quality of life in amaXhosa PLWHA[241,242]. The translation of the MOS-SF-36 had overall good reliability and validity. However, there was poor reproducibility in some questions and the semantics were of concern. Therefore, the authors recommended more research is carried out on this translation[242].

The EQ-5D[243] was designed as a self-report measure of HRQoL for any disease across countries. It assesses five dimensions of health, comparing present state of health to previous state of health and a VAS assessment of current health state[243]. The five domains include mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each domain has three statements to describe participants' current health, which are used to provide a single score, the EQ-5D Index score. Current health state is assessed using a scale where 0 is the 'worst imaginable health state' and 100 is the 'best imaginable health state' which provides an EQ-5D VAS score[243].

The EQ-5D has construct validity, test-retest reliability and responsiveness, particularly to health deterioration, and has been used in people with chronic pain[244–246]. Further the EQ-5D–Xhosa is reliable and validated[241] and has been used in South African urban areas amongst amaXhosa PLWHA[46,72].

2.5.4 Self-efficacy

In determining the effect of self-management programmes, measuring self-efficacy is necessary as it is believed to be integral to the programme's success[77]. The Self-efficacy for Managing Chronic Diseases Six-Item Scale (SE-6)[162,247], Pain Self-Efficacy Questionnaire (PSEQ)[248] and the HIV Symptom Management Self-Efficacy for Women Scale (HSM-SEWS)[249] are three of many valid and reliable self-efficacy scales[162,248,249]. Although the PSEQ was developed for people with chronic pain[248] and the HSM-SEWS for women LWHA[249], and therefore both appear appropriate for assessing change in self-efficacy in women LWHA with pain, isiXhosa versions of the instruments do not exist. Further, the HSM-SEWS, would be problematic for comparison of results between gender[249].

As HIV/AIDS is a chronic disease, the SE-6[162,247] is appropriate for use amongst PLWHA[9]. Further, it has been used in self-management programmes, such as the PL programme amongst PLWHA[46,47,169], to measure change in self-efficacy[162]. The mean average of the six questions, making up the instrument, answered on a scale of one (not at all confident) to ten (totally confident) determines the total self-efficacy score[247]. The SE-6-Xhosa is validated and has single factor structure with good internal consistency[7]. For a combination of these reasons the SE-6-Xhosa is the measurement instrument of choice for evaluating self-efficacy changes in the present study.

2.5.5 Physical function

Pain changes individuals' physical performance and their ability to participate in daily activities[78,250]. PLWHA, and experiencing pain, have lower performance levels than their healthy counterparts[78,250]. Recent Consolidated Standards for Reporting Trials (CONSORT) and Outcome Measures in Rheumatology (OMERACT) groups recommend that both patient reported measures and performance based outcomes should be used in pain studies as they are complementary and provide more comprehensive measurement of physical function. Additionally, a broader assessment of physical function should be made, assessing physical function in light of participation and other inter-related International Classification of Functioning, Disability and Health (ICF) elements[251].

The physical performance task battery (PPTB) is a performance based outcome measuring physical function using a set of familiar simple and complex physical function tasks measured in time, distance or speed[78,252]. The BPI, already chosen as an outcome measure for pain, provides a patient reported measure for physical function by measuring pain interference[251].

The PPTB has been tested amongst people with back pain, people living with cancer and PLWHA and each test was reliable and valid[78,252,253]. The PPTB outcome measure is appropriate for specific conditions as the functional tests included in the battery differ depending on the condition it was tailored for[78,251,252,254,255]. The tests measure speed and co-ordination, balance, and endurance[78,252] and have been used to identify differences in function between PLWHA and healthy people[78]. Testing different aspects of function with a variety of tests provides a broader assessment than if one test was performed independently, such as the six-minute walk test (6MWT), which is included in the PPTB[251]. Further, there is a moderate correlation between performance in the battery of tests and participants' self-report on function ($r = 0.25 - 0.51$)[252]. Of the self-report measures, the Functional Status Index yielded the strongest correlation[252].

As the functional tests are valid as individual tests, the battery can be tailored towards the context of participants and treatment (by omitting irrelevant or unhelpful tests), which is a further strength of the outcome[251,252]. As the coin test, was found to be the least consistent test in one study[252] it was not included in the battery used for the present study. The sock test was also omitted as it measures dexterity and is therefore not a valuable test for measuring the effect of the exercise programme developed by Parker and colleagues[46], which focused on endurance, strength and flexibility. Further, in a previous South African study by Saw and colleagues[192], the sock test was not useful for determining the effect of a similar exercise programme on function. Although the PPTB is time consuming (between 20-40 minutes depending on participants), it is accepted by patients, simple to execute and feasible in resource-poor settings, such as rural South Africa[55,56], as few resources are required[252].

For the purposes of the present study the PPTB included the following tests:

- 15 metres (m) walking at preferred speed. For this test, subjects are timed as they walk 7.5m, turn around, and walk back to the starting position at their preferred walking speed.
- 15 m walk at fastest speed. Subjects are again timed as they walk 7.5m, turn around, and walk back to the start as fast as they can.
- Unloaded forward reach. For this test, subjects stand adjacent to a wall on which a tape measure is positioned horizontally at shoulder height. Subjects reach forward as far as they can and the distance reached is measured in centimetres (cm).
- Timed, repeated sit-to-stand. Subjects sit in a standard chair and are then timed as they stand up and then sit back down, twice. The test is repeated after a brief rest and the average time of the two trials is used.
- Loaded forward reach. For this test, subjects stand adjacent to a wall on which a tape measure is positioned horizontally at shoulder height. They hold a weighted bar (4.5 kg) with both hands close to their body and at shoulder height. They then reach forward as far as they can with the bar in a horizontal position, maintaining their hands at shoulder height. The reach distance is recorded in cm.
- Timed, repeated reach-up. For this test, subjects stand facing a wall and reach up as high as they can with both hands. A mark is placed on the wall at the reached distance. Subjects then reach up and return their hands to their sides three times, as fast as they can.
- Distance walked in 6 minutes. Subjects walk as far and as fast as they can for 6 minutes. The distance walked is measured in metres at 6 minutes. (Subjects are allowed to rest if and as necessary during the 6-minute period.)
- Timed belt tie. Patients sit in a standard chair and are timed as they wrap a standard wrap bandage (approximately 1 meter long) around their waist and tie it in front of them.

2.5.6 Health Literacy

The Rapid Estimate of Adult Literacy in Medicine (REALM) and the Test of Functional Health Literacy in Adults (TOFHLA) or S-TOFHLA are commonly used health literacy measures[190]. The S-TOFHLA has good reliability and validity and is the most appropriate for testing the understanding of information[256].

Individual questions and demographics were measured against the S-TOFHLA using regression analysis to determine the highest predictors of limited health literacy, of which three questions were identified[97]. The questions asked for self-reported reading ability, how much help was needed to read health materials and the level of education obtained. In response to these three questions, the answers more indicative of having limited health literacy were a low self-reported reading ability, needing help frequently when reading health materials (Single Item Literacy Screener (SILS)) or a low level of education. The combination of these three questions is more comprehensive than using the SILS alone, as all three questions are predictors of limited health literacy[97]. The three questions were used to develop a shorter outcome measure than the 36-item S-TOFHLA, called the "SOS" health literacy screening tool[97].

The acronym "SOS" is a helpful mnemonic to remember questions related to: 'Schooling level', 'Opinion of reading ability' and 'Support needed'[97]. Reporting a completion of high school or less, indicating a reading ability of 'okay' or worse and stating that help is 'sometimes' or more often required to understand information on health is indicative of having a limited health literacy[97]. Although the "SOS" health literacy screening tool has not been translated into isiXhosa or studied in an amaXhosa population it will be used to measure health literacy in the present study as it is quick to use, simple to administer and there are no foreseen problems with translation.

2.6 Conclusion

The prevalence of pain amongst rural amaXhosa women LWHA is likely to be high, similar to the high prevalence of pain which exists for urban amaXhosa women LWHA[7,8]. As pain is largely undermanaged in PLWHA[24], especially for women and people with lower levels of education[18,20,26–28], and South Africa has the largest population of PLWHA internationally[1], managing pain well in PLWHA should be of high concern in South Africa. The extent of this problem is increased by the rising prevalence of HIV despite the incidence reducing, a consequence of the successful ART rollout[30] and HIV/AIDS becoming a chronic debilitating condition[9]. Further, is it not simply managing pain which needs research, but the effect pain has on various aspects of health, such as HRQoL, self-efficacy and depression, which also deserve attention[2,4,6,9,16,17,38,41,60,72–79].

Literature infers the lack of and need for effective pain management for PLWHA[18,19,21–24,27]. Turning primarily to non-pharmacological interventions to manage pain in PLWHA is vital, due to the limited efficacy of pharmacological interventions for managing pain in HIV/AIDS[22,80] and the biopsychosocial dynamics of pain[2,16,18,20,21,23,27,60,61,257].

The PL programme, a combination of education and physical exercise, within a similar format to a self-management intervention and based on the principles of CBT[46,47], appears to be an effective alternative for managing pain compared to other pharmacological and non-pharmacological interventions used alone[75–77,138–140,144,145,147,148,162,169,170,175–177]. PLWHA who participate in the PL programme should benefit from knowledge acquisition, increased self-efficacy[164,165] and moderate intensity exercise, which is safe for PLWHA[147,148]. All of these aspects of the programme may bring about pain reduction[76,77,140,144,162,170,177].

The PL programme has been identified as an effective non-pharmacological intervention for managing pain in urban amaXhosa women LWHA[46]. In this cohort pain severity and pain interference was significantly improved. In addition, it appears to be feasible in a resource-poor, rural setting and has moderately long-term effects[46].

Further research is recommended to critically assess the effectiveness and feasibility of the PL programme in rural amaXhosa women LWHA[46]. Although, it is likely to be appropriate for rural amaXhosa women, who share parts of the urban amaXhosa culture[40], rural amaXhosa women may respond differently as a result of biopsychosocial differences. As highlighted in the review, the differences between urban and rural amaXhosa women in culture, level of education and psychosocial constructs need to be considered[34,40–45]. Research also suggests that an empathetic therapeutic relationship may have added to the improvement in pain in urban amaXhosa women LWHA who participated in the PL programme but the extent of the effect of the therapeutic relationship on pain in PLWHA is unknown[46].

In conclusion, a study on the effectiveness of the PL programme is indicated in rural amaXhosa women LWHA. Secondly, the study needs to be designed to allow comparison of the combination of the PL programme with a therapeutic relationship and a therapeutic relationship alone to establish the extent of the effect of the therapeutic relationship on outcomes of the study in Parker and colleagues[46].

3 Chapter Three: Methods

This chapter outlines the methods for the study designed to explore the following aim: “To determine the effect of the PL programme and therapeutic relationship combined intervention (PL intervention), in comparison to a therapeutic relationship intervention (TR intervention) on primary outcomes, pain severity and pain interference, and secondary outcomes, symptoms of depression, HRQoL, self-efficacy and physical function, in rural amaXhosa women LWHA.”

3.1 Research design

A two-group single-blind (by interviewer) stratified convenience trial, with interviewer administered questionnaires and functional tests at Baseline and at Weeks 4, 8, 12 and 24, was conducted.

3.2 Sample

The present study used a sample of convenience of amaXhosa women LWHA, aged between 18 and 40 years and either on consistent ART for three months and registered on the Zithulele Hospital ART database or being monitored for their condition. All amaXhosa women LWHA who attended on the day of the ARV outreach clinics of Zithulele Hospital, in the OR Tambo District, at Pumalanga Clinic and Ngcwanguba Community Health Centre (CHC) were invited to participate in the study. These clinics, Pumalanga Clinic and Ngcwanguba CHC, were chosen as each is well situated with frequent public transport services, facilitating patient access. The sample was not intended to represent all amaXhosa women LWHA in rural areas.

3.3 Sample size and power analysis

Sample size was calculated using change in pain severity on the BPI, a primary outcome measure of the present study. The mean (M) and standard deviation (SD) scores of the PSS in the previous study using the PL programme by Parker and colleagues[46] were used to calculate the present study sample size. The changes in PSS in the previous study by Parker and colleagues[46] were recorded at baseline (5.32 ± 1.93), week 0 (5.55 ± 1.65), week 4 (3.81 ± 2.89), week 8 (3.1 ± 3.03), week 12 (2.79 ± 3.38) and week 16 (1.81 ± 2.87).

A change of three points in pain severity (on a scale from 0 - 10) is regarded as a clinically significant improvement in pain[224,258], hence a minimum detectable difference value of three was used to calculate the required sample size. A sample size of four, six and thirteen participants per intervention group for a SD of 1.6, 2 and 3 respectively was calculated to be statistically significant ($p < 0.05$) and provide a 93%, 92% or 91% power respectively, to detect a three out of ten change in pain severity. Therefore, the power analysis indicated that a sample of 13 participants per intervention group, using the conservative estimate SD value 3, would render adequately powered results.

The sample size was increased after the power analysis to account for potential dropout in the group. In the previous study by Parker and colleagues[46], non-attendance ranged between 8% and 25% of the participants at PL programme weeks and data collection points. The number of participants in the PL intervention group also needed to be increased in order to ensure that each group was large enough for an appropriately sized group of 12 participants[46]. Therefore, the present study needed 24 participants in the PL intervention group in order that two appropriately sized groups of 12 participants could be made for the PL programme. The combined PL intervention group aimed to consist of 24 participants, which allowed for attrition as well as two appropriately sized PL programme groups. An additional 24 participants were therefore to be allocated to the TR intervention group, making the entire sample 48. The power estimates were re-calculated with 24 participants in each group. For SD scores 1.6, 2 and 3 the results would be adequately powered at 100%, 100% and 98% respectively.

3.4 Inclusion and exclusion criteria

Women LWHA who met the criteria for participation in the study, outlined in Table 3-1, were recruited to take part. As discussed in the literature review, PLWHA using or not using ART experience pain[8,24], therefore both of these groups were included in the study. However, in order to ensure stability of participants at Baseline, if those included in the present study had not been on a consistent regimen for three months, they were excluded. Patients were not excluded based on CD4 T-cell count, stage of disease or pain medication use to increase generalisability. However, these parameters were recorded.

Table 3-1: Inclusion and exclusion criteria for participation in study

Inclusion criteria Any woman who:	**Exclusion criteria** Any woman who:
1. is ambulant, HIV+, amaXhosa and aged 18-40 years.	1. is on ART but has yet not been on his/her present treatment regime consistently for three months.
2. attends Pumalanga Clinic or Ngcwanguba CHC for ART or is being monitored for their condition at the clinic.	2. has previously participated in an education and/or exercise intervention to instil skills for managing pain.
3. answers "yes" to the first question on the BPI: "Throughout our lives most of us have had pain from time to time (such as minor headaches, sprains, toothaches). Have you had pain other than these everyday kinds of pain during the last three months?".	3. is considered unfit for exercise according to the American College of Sports Medicine (ACSM) guidelines[259,260].
	4. has a cognitive impairment or moderate to severe intellectual disability as assessed by a medical-officer and occupational therapist using clinical judgement and the Mini Mental State Examination or Allen Cognitive Level Screen Assessment where appropriate.

3.5 Outcome measures

A validated isiXhosa-translation of almost all outcome measures was used and interview administered. Only the "SOS" health literacy screening tool for the assessment of health literacy was not available in isiXhosa and was translated by the research interpreter to ensure consistency. The demographic questionnaire (Appendix A; p.234) and the "SOS" health literacy screening tool (Appendix B; p.236) were interview-administered at Baseline only, while all other measurement instruments were administered at Baseline and each follow-up interview.

The primary outcome of pain was measured by the BPI, which generates a pain severity score and pain interference score (Appendix C/1; p.237)[227]. Symptoms of depression were measured with the BDI (Appendix C/2; p.241)[235]. Health-related quality of life was measured by the EQ-5D, which measures an EQ-5D Index score and an EQ-5D VAS score (Appendix C/3; p.245)[243]. Self-efficacy was measured with the SE-6 (Appendix C/4; p.253)[247]. Physical function was assessed by the PPTB, a physical performance battery of objective tests (Appendix C/5; p.255)[254].

The "SOS" health literacy screening tool was used as a health literacy screen in the present study. The "SOS" health literacy screening tool has not been translated into isiXhosa or studied in an amaXhosa population. This was partially addressed in the present study.

3.6 The intervention

The study included two intervention groups, the PL intervention group and the TR intervention group. The PL intervention group received two interventions, as they participated in the PL programme and the TR intervention. The TR intervention group only received the TR intervention. A diagram indicating the different roles and responsibilities for the implementation of the PL intervention group and TR intervention group can be found at the end of this section (Figure 3-1; p.91).

3.6.1 The 'Positive Living' programme

Participants of the PL programme attended a peer-led group, which met over six consecutive weeks for two hours per week and was guided by the PL workbook (Appendix D; p.257). Each participant received both the English and isiXhosa versions of the workbook (printed in black and white), as participants in the previous study on the PL programme expressed that having both language versions improved comprehension[7]. Participant attendance was recorded on a register.

Peer-leaders, who were HIV-positive, were identified by managers in the Zithulele Hospital ART programme. The two prospective peer-leaders identified were chosen as they were each well respected by community members, had dynamic, influential and encouraging characters, and had previous history of leadership in the ART programme. Both candidates had previously worked as peer-educators, educating peers on LWHA by spoken information provision during support groups. Once identified and chosen, both of the prospective peer-leaders were trained to facilitate the 'Positive Living' programme. One of the trained peer-leaders was unable to follow through on her commitment to the study and 'Positive Living' programme due to personal reasons. Therefore, the remaining trained peer-leader became the facilitator of the groups.

Training of the prospective peer-leaders was conducted by the researcher and took place in January and February 2015 over four weeks and incorporated 40 hours of training (ten hours per week). Before training began, the prospective peer-leaders were given the PL workbook to familiarise themselves with and an orientation into what would be required of them as peer-leaders in the study. The training was done at Zithulele Hospital and Pumalanga clinic, where the intervention would take place. As the researcher was not fluent in isiXhosa, two training assistants were chosen to help with training. The two training assistants each had the greatest amount of experience with interpreting out of the hospital staff. Additionally, one training assistant was an ARV clinic co-ordinator and had previous experience with training peer-leaders to facilitate groups. The role of the two training assistants was two-fold. One responsibility was to aid understanding between the researcher and the peer-leaders in communication by interpreting when necessary. The second responsibility was to ensure that the content of the book and meaning of the message were not lost when the peer-leaders practiced the PL programme facilitation.

As the prospective peer-leaders' previous role as peer-educators had been more didactic in nature and additionally included some counselling, it was imperative that the peer-leaders first understood their new roles in the present study. The pedagogical approach in the PL programme was of facilitated experiential learning, which both candidates were able to demonstrate over the process of training.

Peer-leaders were trained to do group facilitation, use the workbook as a guide and be familiar with its contents. During this process the candidates learnt not to rely on previous knowledge from their role as a peer-educator or to use a didactic approach. Training covered how to start a session, facilitate discussion on workbook educational topics, lead exercise routines and recognise adverse symptoms of exercise, facilitate relaxation techniques, and facilitate action planning and its modification. During training, each week's session was conducted by the researcher in English and observed by the peer-leaders, who afterwards would run the session in isiXhosa to practice until the standard of facilitation was high. Areas within the session would be revisited to allow for improvement. During facilitation by the peer-leaders in isiXhosa, the training assistants' role was essential for achieving a high standard of facilitation.

The outline of topics, content and activities included in the PL programme for Weeks one to six are presented in Table 3-2. Week one of the PL programme commenced with a discussion on maintaining group confidentiality and signing contracts (Appendix E; p.328) to promote commitment to the group members and to attendance. After each session, the peer-leader was debriefed by the researcher to ensure content veracity and peer-leader skill maintenance by making recommendations for the following sessions. Further, the debriefing served as a time for the researcher to provide support to the peer-leader.

Table 3-2: Outline of the PL programme over Weeks one - six

Discussion topic	**Content**	**Action planning**	**Exercise routine**	**Relaxation**
Week one: Self-management and exercise	What is meant by "self-management"? Self-management steps Action plans Exercise Types of exercise Steps to success with exercise An exercise routine	Exercise	-	Included
Week two: Managing common symptoms of HIV/AIDS	Symptom management Action charts for common symptoms Coughing Depression Diarrhoea Fever Headache Eye Nausea and vomiting Shortness of breath Sore throat and mouth Skin problems Urination problems	Managing symptoms + exercise	20 minutes	Included

Discussion topic	Content	Action planning	Exercise routine	Relaxation
Week three: Stress management	What is stress? Managing stress Sleep Communication with your health carer Relaxation skills	Stress management + exercise	22 minutes	Included
Week four: Pain	Causes of pain in HIV/AIDS Pain self-management	Pain + exercise	24 minutes	Included
Week five: Eating well	Balanced nutrition Dealing with barriers to eating well Food safety	Eating well + exercise	26 minutes	Included
Week six: Continuing as a successful self-manager	Action planning for the future Reflection on changes	Continuing as a successful self-manager	28 minutes	Included

[46,47]

Each session had an educational discussion topic, on which participants would develop an action plan. The action plans facilitated skill development, which influences self-efficacy as described in the literature review (Chapter 2.4.2.2; p.42). For Week one an action plan was developed for exercise, which over the programme was reviewed and re-developed weekly. Other action plans corresponding to the topic focused on during a session were reviewed the week after the topic was discussed.

Participants took part in an exercise routine from Week two onwards, which followed the routine provided in the workbook and was amended weekly by adding two minutes of a new exercise. A relaxation session took place at each weekly session of the intervention to facilitate practicing relaxation using one of two relaxation strategies outlined in the workbook. The six-week course concluded with a certificate of graduation.

3.6.2 The therapeutic relationship intervention

Participants from both intervention groups were assessed by the same empathetic research assistant (RA) at data collection Weeks 0, 4, 8, 12 and 24. A therapeutic relationship developed during the interaction between participants and the RA, facilitated by the interview administered questionnaires. As the TR intervention group received this intervention only, the results from this group determined the effects of the therapeutic relationship independently on pain and other outcome measures.

The RA was chosen because she possessed the ability to show empathy and develop a therapeutic relationship. The factors contributing towards a therapeutic relationship are outlined in the literature review (Chapter 2.4.2.6; p.62). Additional training helped the RA to understand and develop how to purposely generate a therapeutic relationship and to maintain the therapeutic relationship with participants over the study period.

Training was done by the researcher (a qualified physiotherapist) during January and February 2015. The RA was trained over 12 hours, during three sessions, before the intervention began. Thereafter, contact with the RA was made before and after each data collection day to review important aspects of the training and to address questions which the RA had, as well as to debrief the RA. The researcher was also available during the data collection days for any questions which arose. Training of the RA encompassed developing skills to perform the interview-administered questionnaires whilst displaying an empathetic relationship. To enhance the empathetic relationship, training included developing empathy, communication skills, interpersonal skills and self-awareness to enhance therapeutic relationship building with participants.

The RA was trained to show care for the participants. This care included encouraging attendance at data collection appointments and showing interest in participants through phone calls for follow-up date reminders, and gently and kindly asking the reason when participants were unable to attend. Further, empathy was developed by training the RA to be able to shift perspective and develop understanding of the participant's experience in order to reflect the participant's experience back to the participant and respond appropriately. Part of this training included communication skills training.

Improving communication skills plays a role in the perception of care. Being able to listen for verbal cues and observe and notice non-verbal cues developed the RA's ability to improve the therapeutic relationship[198,208–210]. Further, aspects of the RA's behaviour towards participants was focused on, ensuring that various interpersonal skills were enhanced such as being friendly, confident, empathetic, encouraging and respectful[198,211]. The RA was trained to appropriately greet participants on arrival in a friendly warm manner and by showing genuine interest in the participant which is appropriate for the amaXhosa culture. As the RA was amaXhosa herself, respectful greetings and conversations enquiring after the participant and their family and context came naturally to her.

The RA was also trained in the importance of building trust and facilitating trust by providing confidentiality, privacy and a non-judgmental space for the participant to express themselves. Training of this kind is valuable, as the character and behaviour of the RA, according to literature, have more influence on the TR than that of the patient[195,197].

It was imperative that the RA showed empathy to participants over the whole study period. In order to strengthen and maintain this, in the present study, debriefing occurred after each data collection date to provide a form of support as well as time for self-reflection to increase self-awareness[216,217]. Further, a social worker was also available for the RA for further debriefing as necessary.

As the RA also conducted the interview-administered questionnaires, training included ensuring that the RA was familiar with the outcome measures. The researcher first went through each outcome measure with the RA. Thereafter, the RA practiced the outcome measures on the researcher, who acted as a participant, to ensure that the RA could perform all of the outcome measures with participants in a consistent manner and record data accurately. Various scenarios were played out in order to ensure that the RA could cope with different responses by participants and that the explanations provided by the RA were consistent despite different participants. The manner in which the data were collected was purposely thought through to achieve the perception of empathy by the study participants. Therefore, the data collection was not done only as a task to be completed but created an atmosphere for an empathetic therapeutic relationship and trust to be built.

With regards to the VAS in the BPI, more focus was placed in training how to explain the question if the VAS was not understood. Scenarios were played out by the researcher acting as a participant to train the RA to be able to problem-solve if participants found difficulty in answering questions such as the VAS in the BPI or picking only one answer of three options as necessary in the BDI. Training also addressed re-explaining and ensuring understanding if the numbers given for each question did not make sense in relation to other questions within the BPI, for example if the worst score for pain was a lower score than the average score for pain in the last week. The RA also practiced explaining the term "average" in order to have a consistent explanation if the question was not initially understood. For questions, such as in the BPI and the EQ-5D with multiple options, it was emphasised that only one option should be chosen by the participant and that therefore if the participant responded with two answers the RA would encourage them to choose one option. The PPTB was practiced multiple times in order to ensure that the set-up was equal at each data collection point and that accurate data recording, which was reliable, was collected.

Participant attendance of data collection follow-ups were recorded by a register. Due to many difficulties with patient transport and community events being held on participants' follow-up dates, participants were provided with a second date to attend within seven days of their original data collection date should they not be able to attend the original date. Participants who were unable to attend their follow-up were given the option of doing a telephonic-based interview, in which all outcome measures were completed except the PPTB.

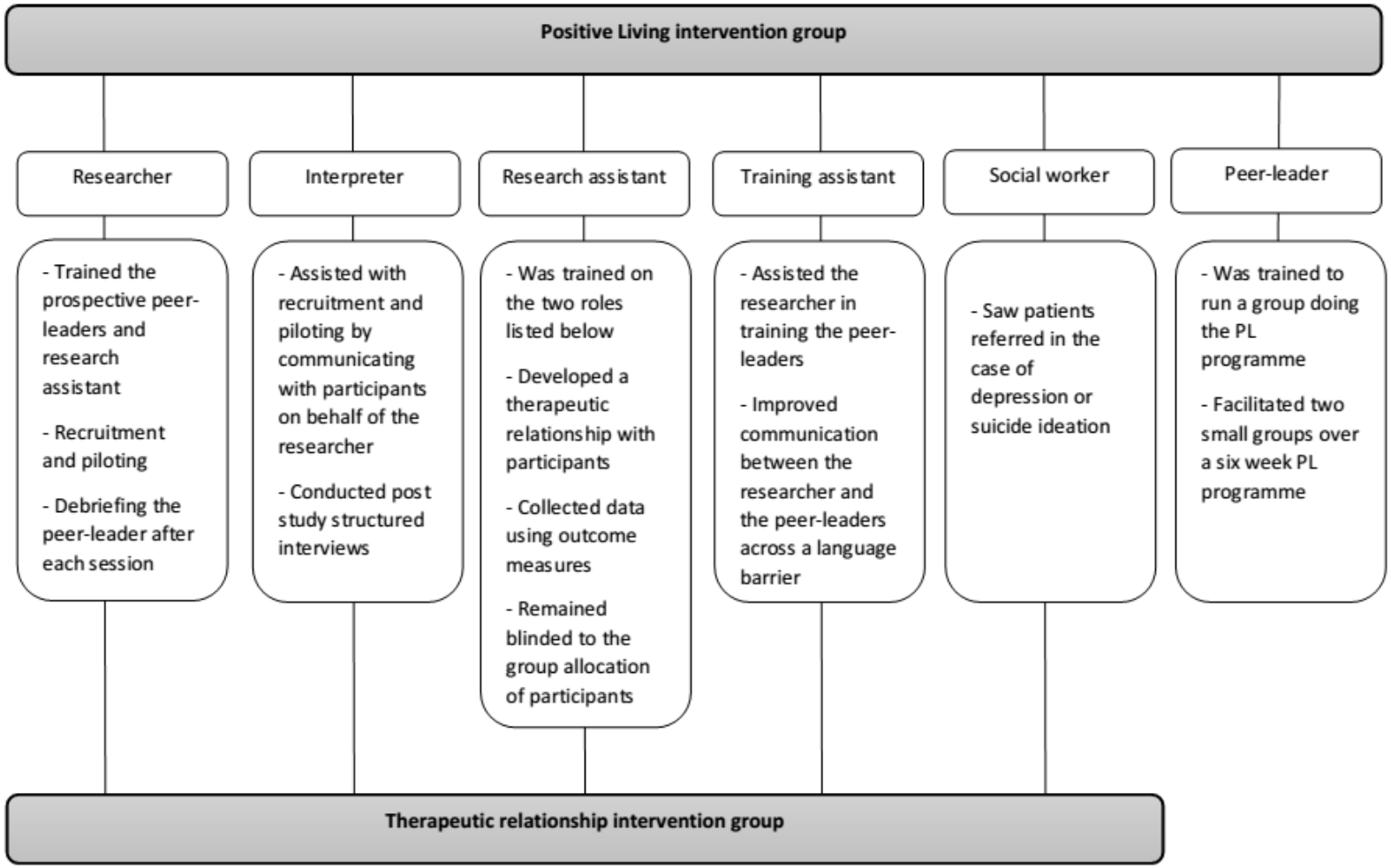

Figure 3-1: Roles and responsibilities for the implementation of the PL intervention group and TR intervention group

3.7 Procedure

The procedure which was followed is illustrated in Figure 3-2 (p.93).

Prior to sample recruitment, the RA, who conducted the interviewer-administered questionnaires for data collection, was trained on all outcome measures. Piloting was performed with five participants (>10% of the proposed sample) to establish whether the recruitment and data collection process was feasible and acceptable for rural amaXhosa women LWHA and it allowed for establishment of inter-rater reliability.

Piloting of the recruitment process was done by the researcher, who was assisted by an interpreter throughout the study, and included the informed consent process and screening for inclusion and exclusion criteria. Thereafter demographic information was collected using the demographic questionnaire and the "SOS" health literacy screening tool was performed. On completion of screening, baseline outcome measures were obtained by the researcher with help from the interpreter for the participants who were piloted only. The outcome measures were repeated by the RA one the same day to establish inter-rater reliability. The results of the repeated outcomes were satisfactory for the most part but one problem was identified, which was that sometimes patients answered the pain severity 'on average' as higher or lower than the 'at its worst' score. This was noted for further analysis when the data collection was complete. In addition, training was done with the RA to develop standard explanations of the term 'average'.

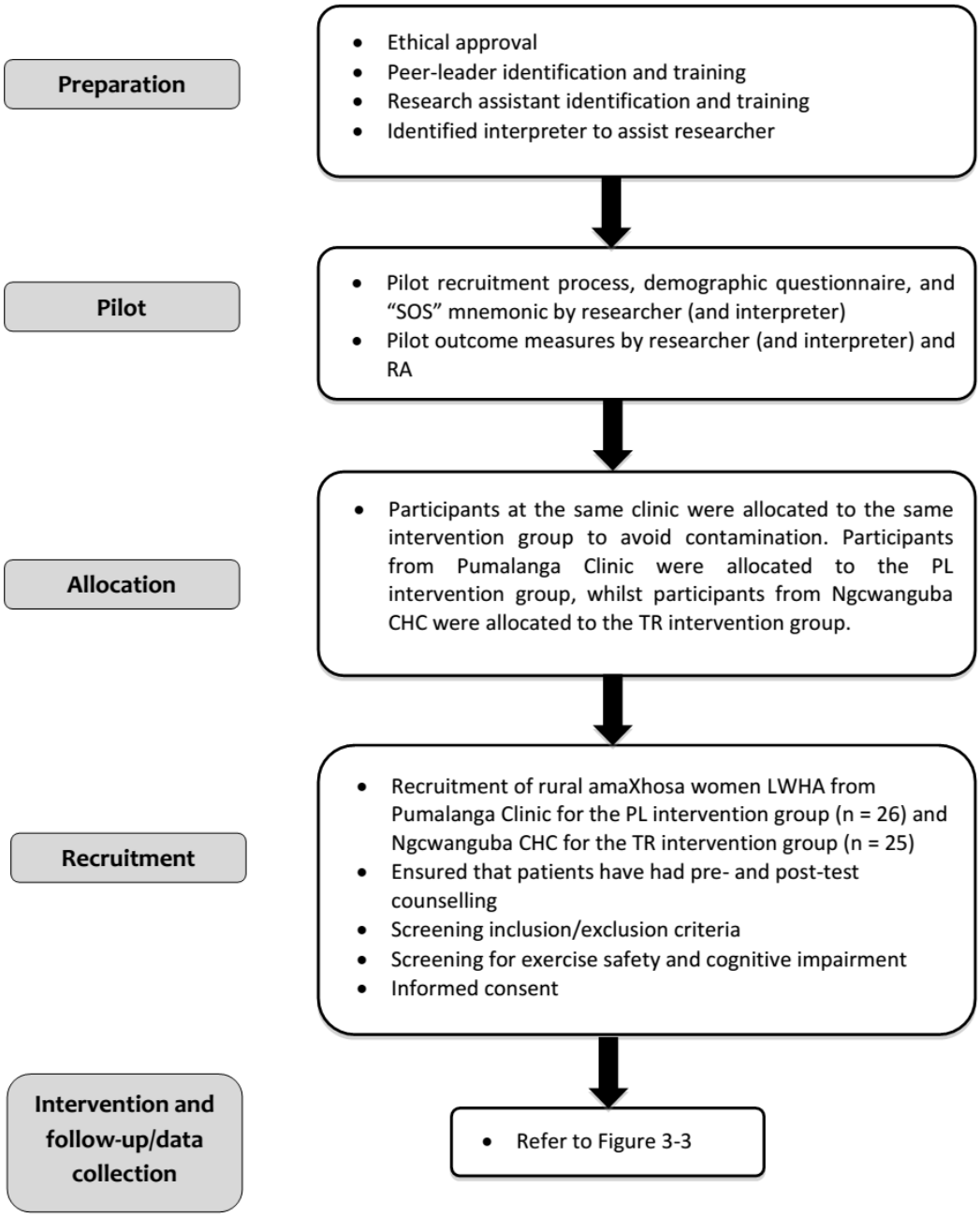

Figure 3-2: Procedure for the study

Thereafter, in February and March 2015, recruitment from ARV clinics at Pumalanga Clinic and Ngcwanguba CHC commenced. Medical officers, nursing staff and word-of-mouth at the clinic directed women LWHA who indicated an interest in participating in the study to a consulting room for the recruitment process. The research interpreter who helped during piloting, interpreted for the researcher during the whole recruitment process. If participants had completed pre- and post-test counselling they were screened for inclusion and exclusion criteria, including completing a screening for exercise safety (Appendix F; p.330) and cognitive impairment. If they were eligible for the study they were invited to participate in the study and the informed consent process was completed. If consent was given the researcher completed a demographic questionnaire and "SOS" health literacy screening tool with each participant. History taking was performed and medical notes in clinical notes and files were reviewed to collect relevant clinical information.

Participants from Pumalanga clinic were allocated to the PL intervention group, while participants from Ngcwanguba CHC were allocated to the TR intervention group. This approach was used to prevent contamination. The two clinics are located far apart geographically, around 20 kilometres of hilly terrain, therefore minimising the interaction between the two communities[261]. By road, either a dirt road of around 23 kilometres or a tar road of 28 kilometres, separate the two clinics[261]. Pumalanga was chosen as the site for the PL intervention group as the setting had a separate venue where the PL programme could run while maintaining blinding of the RA.

Separate information sheets and consent forms were created for the two intervention groups, which were translated into isiXhosa via forward and back translation, to maintain the semantics of the English version. The English and isiXhosa versions are both provided in the appendices (Appendix G; p.331). The consent form was read out by the research interpreter to the prospective participants to ensure that reading ability didn't create a barrier to their understanding the contents of the form. Prospective participants could also take the consent forms home to discuss and decide on participation with family, however no-one took up this offer. The opportunity to ask questions and raise concerns was available during recruitment and at all times during the study.

Participants were informed that all transport costs would be reimbursed as it was an extra expense incurred due to study involvement and the PL intervention group were informed that they would receive a graduation certificate at their final session. Additionally, at data collection points and during the PL programme sessions a small snack and a drink would be provided to help sustenance during the clinic visits.

All participants were given a number by random number allocation, which protected their identity from being linked to data collected, maintaining confidentiality, and assisting with blinding. Participants were explicitly told to keep the intervention group they participated in unknown to the RA. The RA remained unaware of the venue and PL programme sessions and reported being unaware of the participants' allocated intervention.

There were 26 participants recruited for the PL intervention group and 25 recruited for the TR intervention group. The PL intervention group was split into two groups of 12 and 14 for the PL programme. This smaller group size was based on the number of participants in the PL programme group in the study by Parker and colleagues[46,47], as explained in the section on sample size (Chapter 3.2; p.77). All study participants were provided with appointment cards and were reminded telephonically via a cellular phone by the research interpreter of the PL programme dates and by the RA for data collection point dates. Refer to Figure 3-3 (p.97) for procedure and timeline for the PL and TR intervention groups.

After recruitment, participants' baseline outcomes measures were obtained by the RA. Two participants did not arrive for their baseline outcome measures and dropped out of the study leaving 23 participants in the TR intervention group. A week after recruitment and baseline measures were completed the PL programme commenced.

During the PL programme and data collection, if participants did not arrive they were contacted to encourage future participation and remind them of the next date. This helped to minimise missing data, ensure that participants were aware of the next date in order to facilitate continuity in the study, and contribute to developing the therapeutic relationship by indicating care when a follow-up date was missed.

During the study, participants were observed, by the peer-leader and RA, for signs and symptoms of worsening condition, to ensure exercise was always safe or a timeous referral to a medical officer was made if necessary. The peer-leader and RA were trained to alert the researcher if any concerns arose, however no concerns regarding exercise and health deterioration arose.

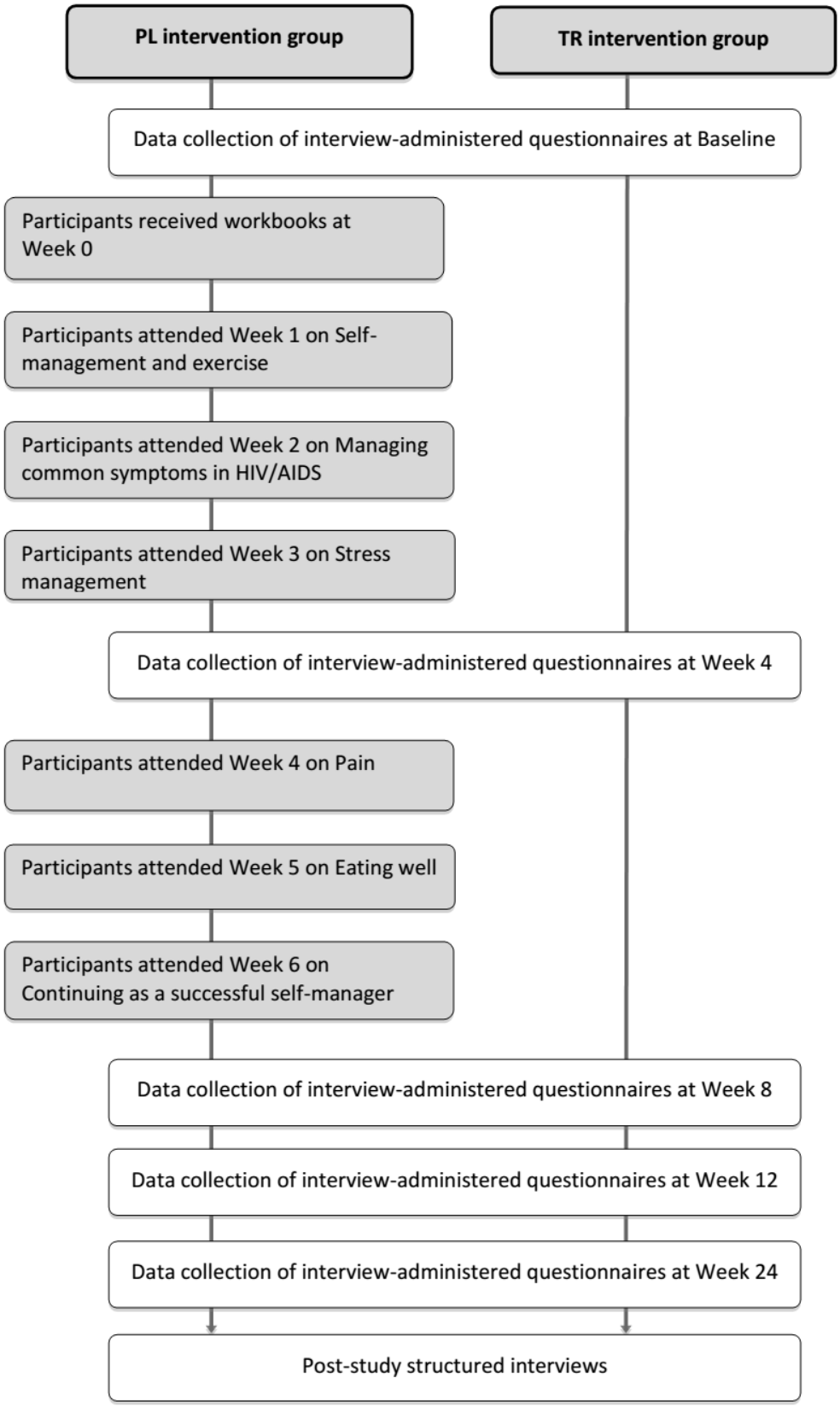

Figure 3-3: Procedure and timeline for the PL and TR intervention groups

The researcher was alerted to any concerns raised by the RA regarding the BDI. The RA was trained to refer participants to a social worker if they presented with moderate to severe depression on the BDI. However, participants who answered "I would like to commit suicide" or "I would commit suicide if I got the chance" were escorted directly to the social worker. If these answers were given over telephone based interviews, then participants were asked to come into Zithulele Hospital and the social worker was given their details immediately to phone them and make a home visit if necessary.

After the completion of the Week 24 data collection point, a post study structured interview was conducted by the research interpreter. The series of open-ended questions (Appendix H; p.358) were asked telephonically, over a cellular phone, and differed for the two intervention groups. The PL intervention group interview questions were relevant to understanding the impact of the PL programme and its workbook and assessing whether further development was needed. Additionally, the PL intervention group post-study interviews were done to discern whether any contamination had taken place. The TR intervention group post-study interview was structured to further identify if any information from the PL programme and workbook had been disseminated to participants in the TR intervention group.

3.8 Ethical considerations

Before study commencement ethical approval was obtained from the Faculty of Health Sciences, Human Research Ethics Committee, University of Cape Town (HREC REF: 932/201) (Appendix I/1; p.361) and the Eastern Cape Department of Health (Ref: EC_2015RP30_713) (Appendix I/2: p.363). Additionally, permission for this research was granted by the Chief Medical Officer at Zithulele Hospital (Appendix I/3: p.364). The researcher is a qualified physiotherapist, registered with the Health Professions Council of South Africa (registration number: PT0116360). Throughout the study, adherence to the principles of the Declaration of Helsinki was maintained[262].

Participation was voluntary and the information sheet and informed consent form contents were verbally communicated to ensure that participants could fully understand irrespective of their reading ability or health literacy, in order to make an informed decision to participate. It was disclosed that participants would participate in one of two intervention groups and that on completion of the study, should it be found that one intervention group received a significantly inferior intervention, participants would be given access to the superior intervention. Participants were informed that they were always allowed to ask questions, raise concerns or withdraw from the study. The Flesch Reading Ease Scores for the information sheet and consent forms of the PL and TR intervention group were 70.1/100 and 71.6/100 respectively. According to the Flesch-Kincaid Grade Level the contents of the informed consent forms for the PL and TR intervention group are readable at a grade 8 and grade 7 level respectively.

Patient confidentiality was maintained by the researcher, research interpreter, RA, peer-leader and participants and all people involved signed contracts to this effect. Only relevant and valuable information for the study were accessed from records and handheld clinic cards. Using coding for the data collection maintained patients' anonymity and the RA sealed data in envelopes, which were only accessible by the researcher. To further protect participants' confidentiality, participants were contacted telephonically over cellular phones instead of using a short messaging service, as some participants shared cellular phones with other people. At closure of the study all data are to be kept in a locked filing cabinet by the research supervisor for five years.

On occasion participants requested to be interviewed alongside another participant. As patient confidentiality is important to ensure and therefore a delicate matter, participants who came forward together requesting to have interviews done together were each asked if they consented to this. In order to ascertain if they were completely willing, participants were asked for their consent individually, and were not in the presence of any other participants at the time of this question. Careful consideration was taken to detect any hesitation disclosed by participants in verbal and/or non-verbal responses.

As there was a risk of participants being recognised by community members as being HIV+ and thereafter experiencing HIV stigma, efforts were made to minimise this risk. The PL workbook's cover had no obvious associations to HIV/AIDS and apart from ARV clinic days being used for recruitment, the venues were not clearly associated with HIV/AIDS. Furthermore, as mentioned previously, confidentiality was maintained throughout.

Compensation was fully disclosed at recruitment and was not compelling in any way to persuade participants to participate in order to receive compensation. Participants were treated equally to all other patients when seeking health care services and given no privileges during standard health care treatment. Monetary compensation covered the exact cost of transport to and from the clinic, enabling those with limited finances to take part and not causing any financial burden.

Participation did not interfere with standard health care treatment and referrals for extra health care were made as appropriate when identified during the course of the study. A social worker was available for those with moderate to severe depression according to the BDI and a plan was put in place for participants if they were at risk of suicide. Screening for exercise safety at recruitment ensured that all participants were safe to exercise and further, the peer-leader and the RA were trained to recognise symptoms of distress during exercise. The peer-leader also ensured the creation of safe action plans.

The intention of the study was to benefit amaXhosa women LWHA with the aim of decreasing pain severity and pain interference by facilitating participants in the PL programme groups towards becoming successful self-managers and to benefit participants by a TR intervention. Potential existed for further benefit by decreasing depression and improving HRQoL, function and self-efficacy. This study was built on previous work in managing pain in PLWHA, in urban amaXhosa women specifically[46] and intended to research options for feasible and effective pain management strategies for rural amaXhosa women LWHA. Furthermore, this research contributed to research establishing effective non-pharmacological pain management in PLWHA, especially in South Africa where the largest HIV+ population lives.

3.9 Data management and statistical analysis

The primary outcome of pain in this study, as measured by the Pain Severity Score and Pain Interference Score of the BPI, using an 11-point VAS, were regarded as ratio variables for groups[263]. As ratio data, the difference between scores on the VAS are meaningful for groups, and the difference between a score of two and three on the VAS is of the same intensity, on average, as the difference between a score of five and six. If Pain Severity Scores have halved it means that pain, on average, is half the pain intensity experienced before[263]. To determine the type of analysis to be conducted, distribution of the primary outcome measure, was tested using the Kolmogorov-Smirnov test. Data were normally distributed ($d = 0.08$; $p > 0.2$) and therefore, parametric statistical analyses were conducted.

Distribution of all other data sets at Baseline were also tested using the Kolmogorov-Smirnov test. Data for age, CD4 T-cell count at diagnosis and recent CD4 T-cell count, symptoms of depression, HRQoL (EQ-5D VAS only), self-efficacy and physical function were all normally distributed. Only the EQ-5D Index data set was not normally distributed.

A pragmatic approach to statistical analysis was followed for ease of interpretation of results. In the pragmatic approach, the distribution of the primary outcome measure is used to guide the analysis across all data[264]. This approach meant that despite the EQ-5D Index data not being normally distributed, parametric tests were still used, guided by the normal distribution of the primary outcomes, and in keeping with the rest of the secondary outcomes. In addition, parametric testing was conducted on the CD4 T-cell counts, in keeping with the pragmatic approach[264], despite CD4 T-cell counts being more commonly regarded as a non-parametric variable[265,266].

Accordingly, results are presented as means (M) and standard deviations (SD) throughout. Descriptive measures such as frequency tables, proportions and Pearson Chi-squared tests ($\chi 2$) were used to analyse categorical data. Box and whisker plots for pain severity and intensity, CD4 T-cell count at diagnosis, recent CD4 T-cell count, and the EQ-5D Index measure of HRQoL can be found in Appendix J (p.369) for depth of presentation.

Mixed model regression was used to test the effects of group, time, and group and time interactions, on pain severity, pain interference, depression, HRQoL (EQ-5D VAS and EQ-5D Index), self-efficacy and independent timed and distance tests of the PPTB. Two-way analysis of variance (ANOVA) was not used to test for significance, as mixed model regression was favourable for repeated measures in the presence of missing data.

For the regression analysis, initial diagnostic tests were performed on individual data sets with missing data to determine that data were appropriate to use regression. If data were not normally distributed as a consequence of missing data, they were transformed as necessary. Regression was used to fit a null model, which each model was then compared with. Four models, which were group, time, group and time, and group and time with a random intercept and slope, were assessed. If significance in a model was found, family-wise p-value correction was performed to test for multiple comparisons and reduce inflation of significance. If multiple models remained significant after correction, comparisons were made using ANOVA to determine the best model. Thereafter, family-wise p-value corrections were repeated. If no significant model was found to be better, the simplest model was chosen. To illustrate change over time ANOVA tests were conducted to accompany the results of the multiple regression analysis.

In cases where no model would fit, such as with the data for the EQ-5D Index and the timed repeated sit-to-stand, the repeated reach-up and the belt-tie tests, analyses was conducted with a t-test and a one-way ANOVA, in keeping with the parametric approach.

Significance was accepted at $p < 0.05$. Analysis was by intention to treat. For mixed model regression and all other analyses, the original data set with missing data was used. All data were captured on a Microsoft Excel spreadsheet. R Version 3.1.2 was used for model regression analysis and included use of the 'ordinal', 'lme4', 'GAMLSS' and 'car' packages[267–271]. The graphs were produced using GraphPad Prism Version 6[272] and the remaining data were analysed by STATISTICA®[273]. The researcher completed all univariate analyses while mixed model regression was carried out by Associate Professor Peter Kamerman from the School of Physiology, University of Witwatersrand.

4 Chapter Four: Results

This section will first present the sample. The attendance of participants at the PL programme and data collection points of the PL intervention group and TR intervention group will follow. Thereafter the socio-demographic and clinical characteristics of the participants, analysis of change of the primary outcome, pain, and secondary outcomes over time will be presented. Lastly, the responses to open-ended post-study interviews will be presented. The results are presented for the sample (N = 49), the PL intervention group (n = 26) and the TR intervention group (n = 23).

4.1 Sample

The study took place from February 2015 and September 2015. In total, 84 women LWHA were screened at Pumalanga clinic (n = 43) and Ngcwanguba CHC (n = 41) for participation in the study. The procedure for recruitment and screening is illustrated in Figure 4-1.

Of the 26 participants in the PL intervention group, the number of attendees fluctuated weekly (Figure 4-2). For data collection points, which all participants attended at Baseline and Weeks 4, 8, 12 and 24, attendance fluctuated for various reasons, as stated in Figure 4-2. There were six participants in the PL intervention group and eight in the TR intervention group who attended all of five data collection points.

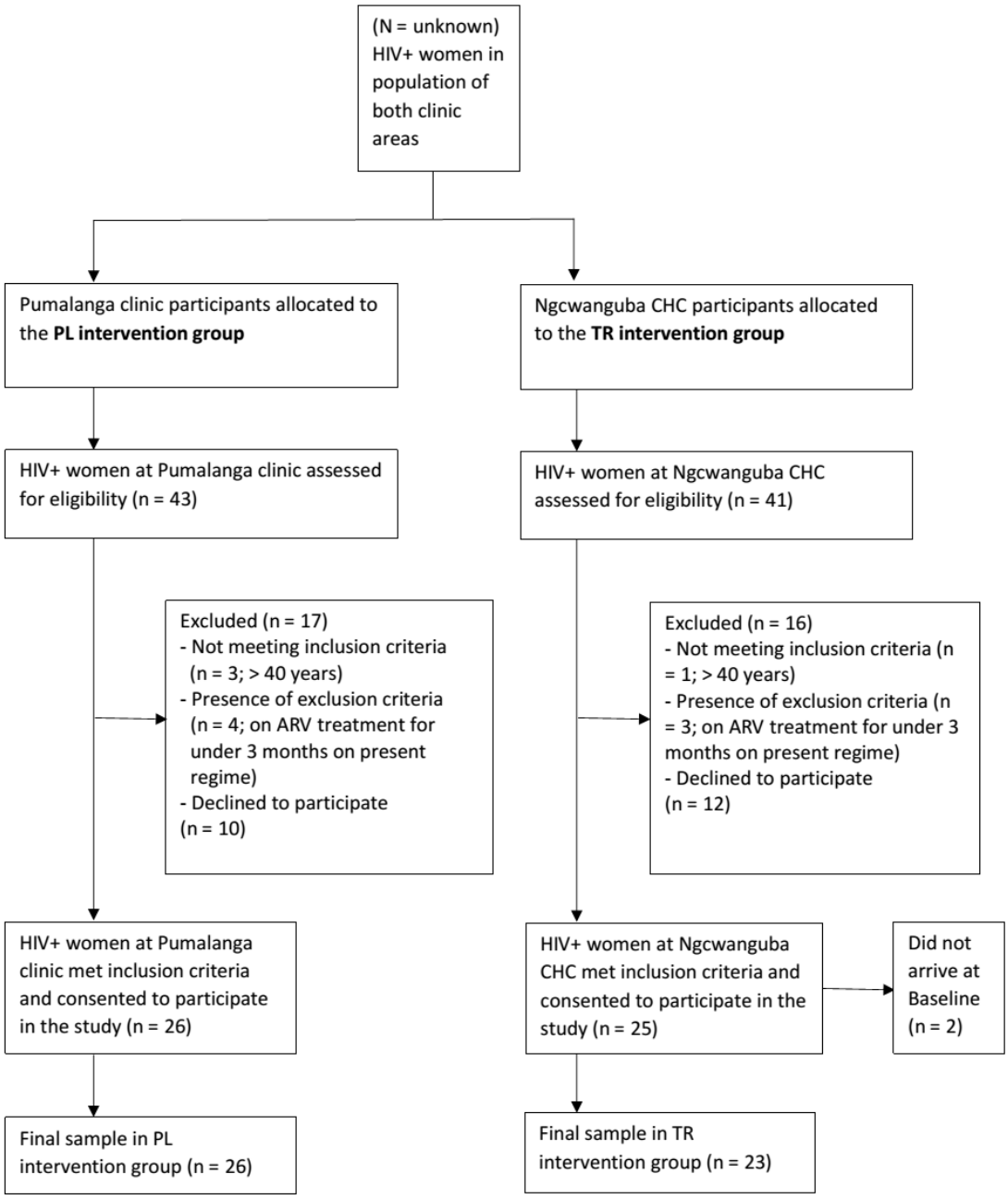

Figure 4-1: Screening, recruitment and allocation procedure

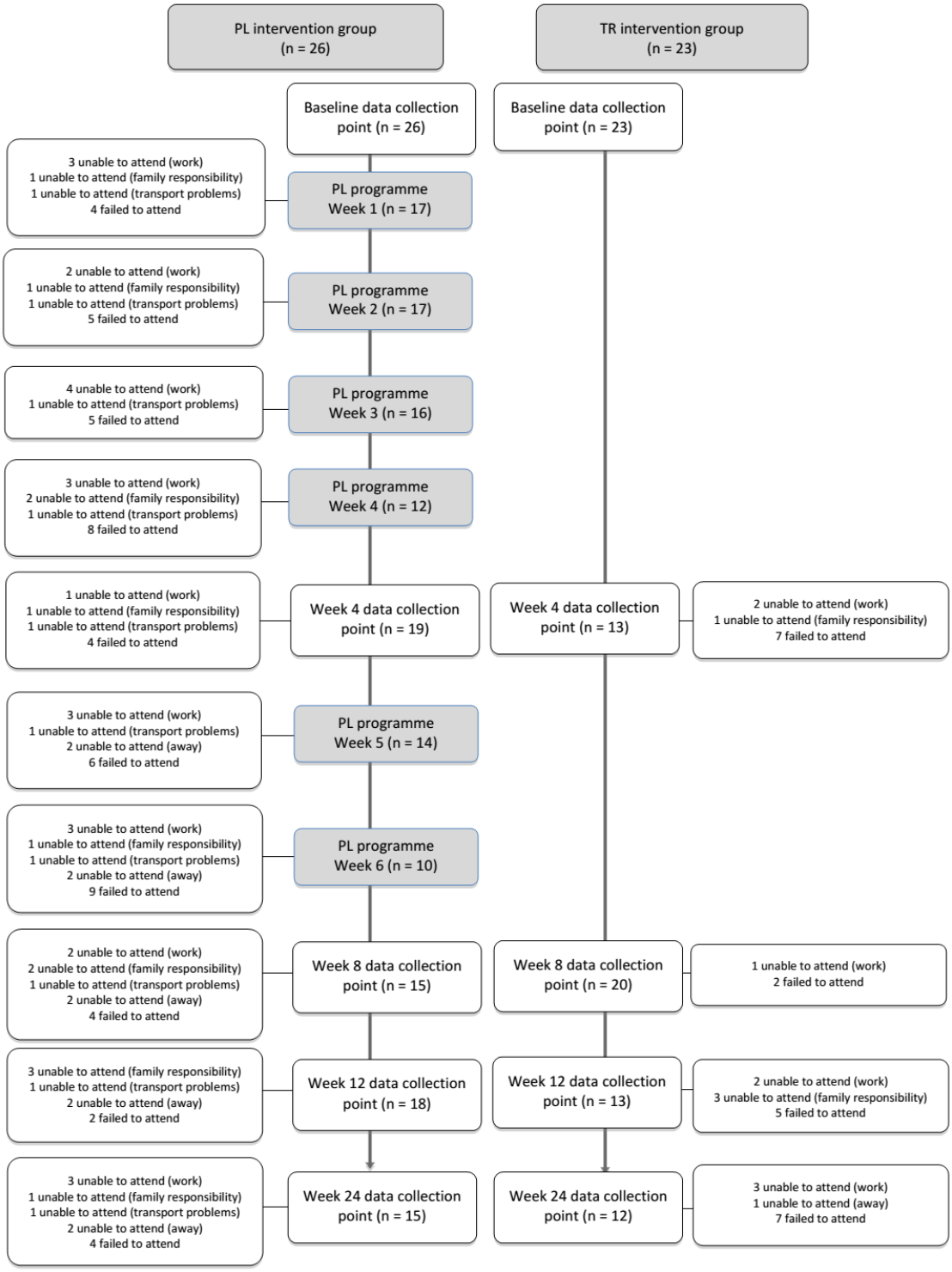

Figure 4-2: Attendance of PL programme and data collection points[b]

[b] The expression 'failed to attend' refers to there being no known reason for non-attendance, as sometimes participants were not reached when contacted.

The results represent the number of participants reported at each data collection point in Figure 4-2 (p.106), except where otherwise stated in the chapter.

4.2 Socio-demographic characteristics

Socio-demographic data were collected in the demographic questionnaire at recruitment.

4.2.1 Age

The mean age for the sample was 33 years (± 5). No significant difference between groups was found for age ($t = 0.72$; $p = 0.48$) between the PL intervention group (33 years ± 5) and the TR intervention group (32 years ± 4).

4.2.2 Employment, highest level of education and health literacy

Unemployment, independent of reason, was the predominant employment status in the sample with over 80% unemployment levels in both groups. Of participants who were unemployed, over 50% were not looking for work. Over half the participants attended high school and the most common highest level of education (HLOE) category was eight to nine years of education (34.7%). All participants had limited health literacy. No significant differences were found between groups for employment status, HLOE and health literacy (Table 4-1).

Table 4-1: Employment status, highest level of education and health literacy of the participants and PL and TR intervention groups (N = 49)

	Participants	**Positive Living intervention group**	**Therapeutic relationship intervention group**	
	Number (%)	Number (%)	Number (%)	Significance Test
Employment	N = 49	n = 26	n = 23	$\chi^2 = 1.42$; p = 0.7
Unemployed - not looking for work	23 (47)	12 (46)	11 (48)	
Unemployed – looking for work	17 (35)	9 (35)	8 (35)	
Employed	8 (16)	5 (19)	3 (13)	
Unable to work – disability grant	1 (2)	0 (0)	1 (4)	
Highest level of education	N = 49	n = 26	n = 23	$\chi^2 = 2.11$; p = 0.55
No schooling	4 (8)	1 (4)	3 (13)	
Gr.1-7	15 (31)	7 (27)	8 (35)	
Gr.8-9	17 (35)	10 (37)	7 (30)	
Gr.10-12	13 (27)	8 (31)	5 (22)	
Health literacy	N = 49	n = 26	n = 23	
Limited health literacy	49 (100)	26 (100)	23 (100)	
Adequate health literacy	0 (0)	0 (0)	0 (0)	

4.3 Clinical characteristics

4.3.1 Medical history

Participants were all HIV positive, as required by the inclusion criteria, with a mean of 3.96 (± 3.25) years since diagnosis and no significant difference between the groups. The mean CD4 T-cell count at diagnosis for the sample was 232 cells/μl (± 95). A significant difference was found for CD4 T-cell count at diagnosis between the PL group (206 cells/μl ± 73) and the TR group (269 cells/μl ± 112; t = 2.13; p = 0.04). However, no significant difference existed between groups at the most recent CD4 T-cell count, with a sample mean of 461 cells/μl (± 239) (Table 4-2).

Table 4-2: Years since diagnosis (N = 48), CD4 T-cell count at diagnosis (N = 39) and recent CD4 T-cell count of the participants and PL and TR intervention groups (N = 45)

	Participants	**Positive Living intervention group**	**Therapeutic relationship intervention group**	
	Mean ± SD (Range)	Mean ± SD (Range)	Mean ± SD (Range)	Significance Test
Years since diagnosis	N = 47	n = 25	n = 22	
Years	3.97 ± 3.25 (0.25 - 13)	4.33 ± 2.56 (0.25 - 10)	3.56 ± 3.92 (0.25 - 13)	t = 0.81; p = 0.42
CD4 T-cell count at diagnosis	N = 39	n = 23	n = 16	t = 2.13; p = 0.04*
Cells/μl	232 ± 95 (32 – 505)	206 ± 73 (32 – 336)	269 ± 112 (36 – 505)	
Recent CD4 T-cell count	N = 45	n = 25	n = 20	t = 0.52; p = 0.61
Cells/μl	461 ± 239 (54 – 1120)	478 ± 251 (54 – 1038)	441 ± 227 (195 – 1120)	

* Indicates a significant difference between groups

4.3.2 HIV management

The participants were primarily on first-line ART while few participants were being monitored (8.16%) or were on second-line ART (10.2%). There was no significant difference between the groups in HIV management ($\chi^2 = 0.42$; $p = 0.81$) (Table 4-3).

Table 4-3: HIV management of the participants and PL and TR intervention groups (N = 49)

	Participants	**Positive Living intervention group**	**Therapeutic relationship intervention group**	
	Number (%)	Number (%)	Number (%)	Significance Test
HIV management	N = 49	n = 26	n = 23	$\chi^2 = 0.42$; $p = 0.81$
Monitoring	4 (8)	2 (8)	2 (9)	
First-line	40 (82)	22 (85)	18 (78)	
Second-line	5 (10)	2 (8)	3 (13)	

4.3.3 History of opportunistic infections

The most common opportunistic infection (OI) reported by participants was pulmonary tuberculosis. Commonly participants were unaware of other OIs and these were not recorded or specified in clinic card records. No significant difference existed between groups for prevalence of opportunistic infections (Table 4-4).

Table 4-4: History of opportunistic infections of the participants and PL and TR intervention groups (N = 49)

	Participants	**Positive Living intervention group**	**Therapeutic relationship intervention group**	
	Number (%)	Number (%)	Number (%)	Significance Test
Medical history of opportunistic infections	N = 49	n = 26	n = 23	$\chi^2 = 6.12$; p = 0.47
Previous pulmonary tuberculosis	10 (20)	2 (8)	8 (35)	
Previous extra-pulmonary tuberculosis	1 (2)	1 (4)	0 (0)	
None known	38 (78)	23 (88)	15 (65)	

4.3.4 Co-morbidities

Co-morbidities were infrequent amongst the participants. In the PL intervention group one participant had depression and another had hypertension. The TR intervention group had one participant with epilepsy. No significant difference was found between the groups (Table 4-5).

Table 4-5: Co-morbidities of the participants and PL and TR intervention groups (N = 49)

	Participants	**Positive Living intervention group**	**Therapeutic relationship intervention group**	
	Number (%)	Number (%)	Number (%)	Significance Test
Co-morbidities	N = 49	n = 26	n = 23	$\chi^2 = 2.91$; p = 0.41
Depression	1 (2)	1 (4)	0 (0)	
Epilepsy	1 (2)	0 (0)	1 (4)	
Hypertension	1 (2)	1 (4)	0 (0)	
None known	46 (94)	24 (92)	22 (96)	

4.3.5 Analgesics

Over half the participants in each group reported not receiving any analgesics. Paracetamol was the most commonly used medication. There was no significant difference between the groups for the use of analgesics (Table 4-6).

Table 4-6: Analgesic use of the participants and PL and TR intervention groups (N = 49)

	Participants	**Positive Living intervention group**	**Therapeutic relationship intervention group**	
	Number (%)	Number (%)	Number (%)	Significance Test
Analgesics	N = 49	n = 26	n = 23	$\chi^2 = 3.12$; p = 0.54
Paracetamol	11 (22)	5 (19)	6 (26)	
NSAIDS	1 (2)	0 (0)	1 (4)	
Paracetamol & NSAIDS	6 (12)	4 (15)	2 (9)	
Paracetamol, mild opioids & NSAIDS	1 (2)	0 (0)	1 (4)	
None	30 (61)	17 (65)	13 (57)	

4.4 Change in pain

4.4.1 Prevalence of pain

As per inclusion criteria all participants had experienced pain within the previous three months. All participants reported pain within the last week on the BPI at Baseline (100% prevalence of pain). By Week 4 the prevalence of pain for the participants had reduced to 63.27%. In the weeks to follow the prevalence of pain continued to reduce until under half of all the participants presented with pain (Figure 4-3).

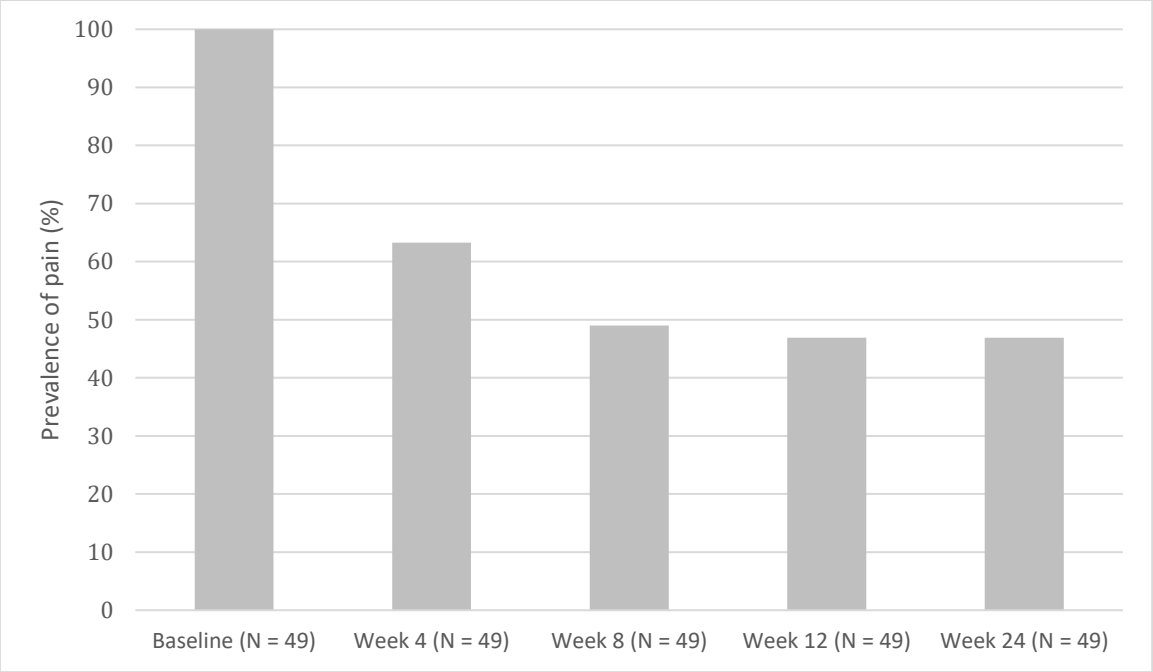

Figure 4-3: Change in prevalence of pain for the sample

The prevalence of pain in the PL intervention group and TR intervention group lowered to 62% and 65% respectively at Week 4. In the PL intervention group, the prevalence of pain continued to reduce, remaining lower than the TR intervention group over Weeks 4 to 24. However, there was no statistical difference between the groups for prevalence of pain at Weeks 4 ($\chi^2 = 0.07$; $p = 0.79$), 8 ($\chi^2 = 0.99$; $p = 0.32$), 12 ($\chi^2 = 1.6$; $p = 0.21$) and 24 ($\chi^2 = 1.6$; $p = 0.21$) (Figure 4-4). Carried forward data was used to determine the prevalence of pain results.

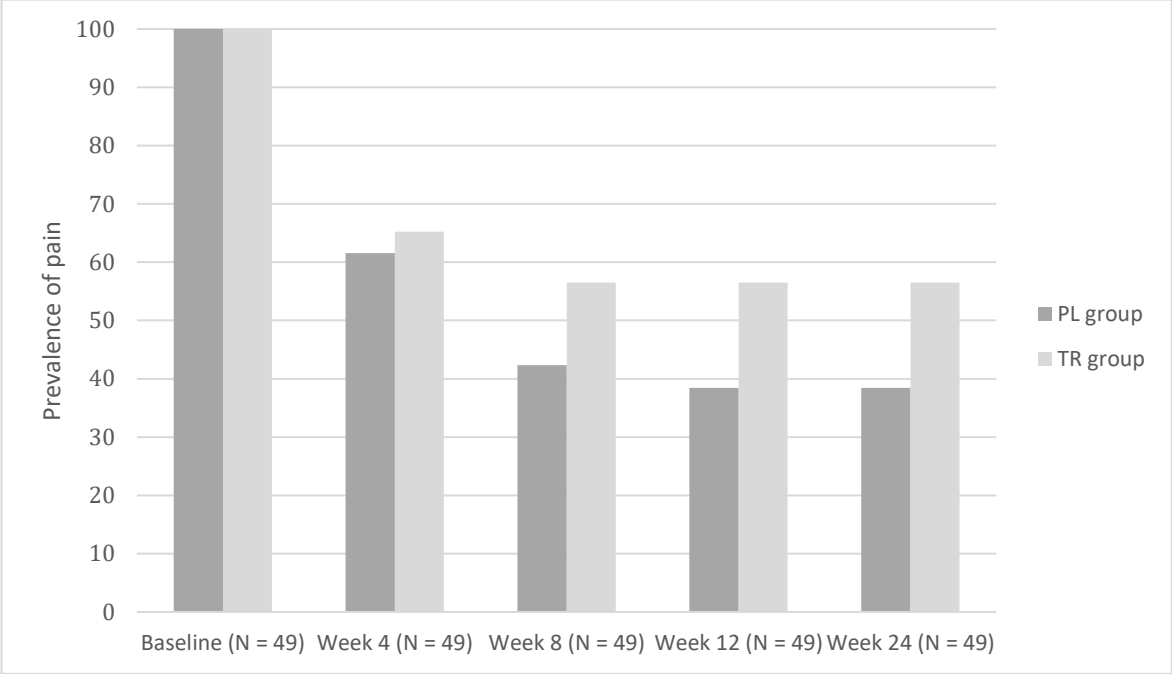

Figure 4-4: Change in prevalence of pain in PL and TR intervention groups over time

4.4.2 Sites of pain

The participants in each intervention group (the PL and TR group) reported a median of 3 (range: 1-6) sites of pain at Baseline. The number of body sites participants reported experiencing pain in are represented in Figure 4-5 and Figure 4-6.

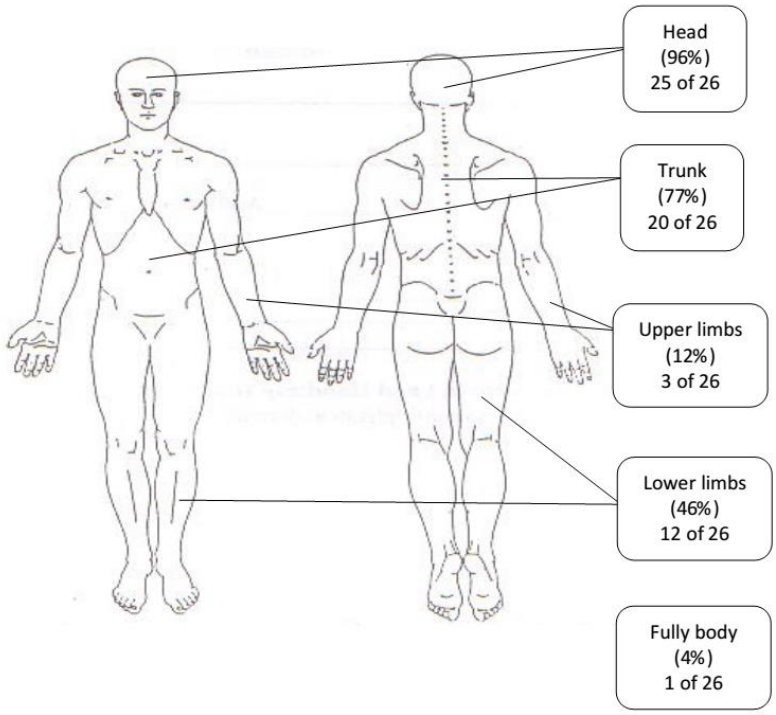

Figure 4-5: Sites of pain in the PL intervention group at Baseline

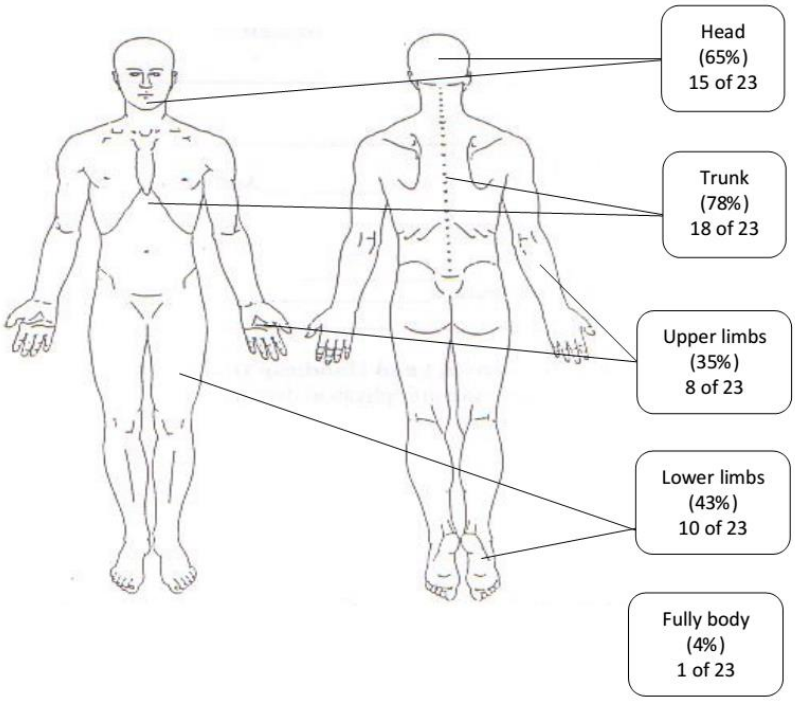

Figure 4-6: Sites of pain in the TR intervention group at Baseline

4.4.3 Pain Severity Scores

The change in PSS over time is presented in Figure 4-7 and PSS at each time point are presented in Table 4-7. No significant difference between groups was found for PSS at Baseline ($t = 1.22$; $p = 0.23$) (Table 4-7). Change in PSS over time was analysed using a cumulative link mixed-model ordinal regression. Three models, including the effect of group, group and time, and group and time with random intercept and slope, were significant when compared with the null model. After family-wise p-value correction the models for group and time, and group and time with random intercept and slope were significant and compared to each other. The best model was the effect of group and time with random intercepts and slopes. On evaluation of this model there was a significant effect of time over the 24 weeks of the study ($p < 0.001$), where over time PSS decreased, indicating improvement. There was no significant effect of group or group and time interaction. Both groups showed significant improvements in PSS over time. In addition, the improvements in PSS over time were also clinically meaningful[263], as the improvement in each group was more than three points on the scale of 0-10 (Table 4-7).

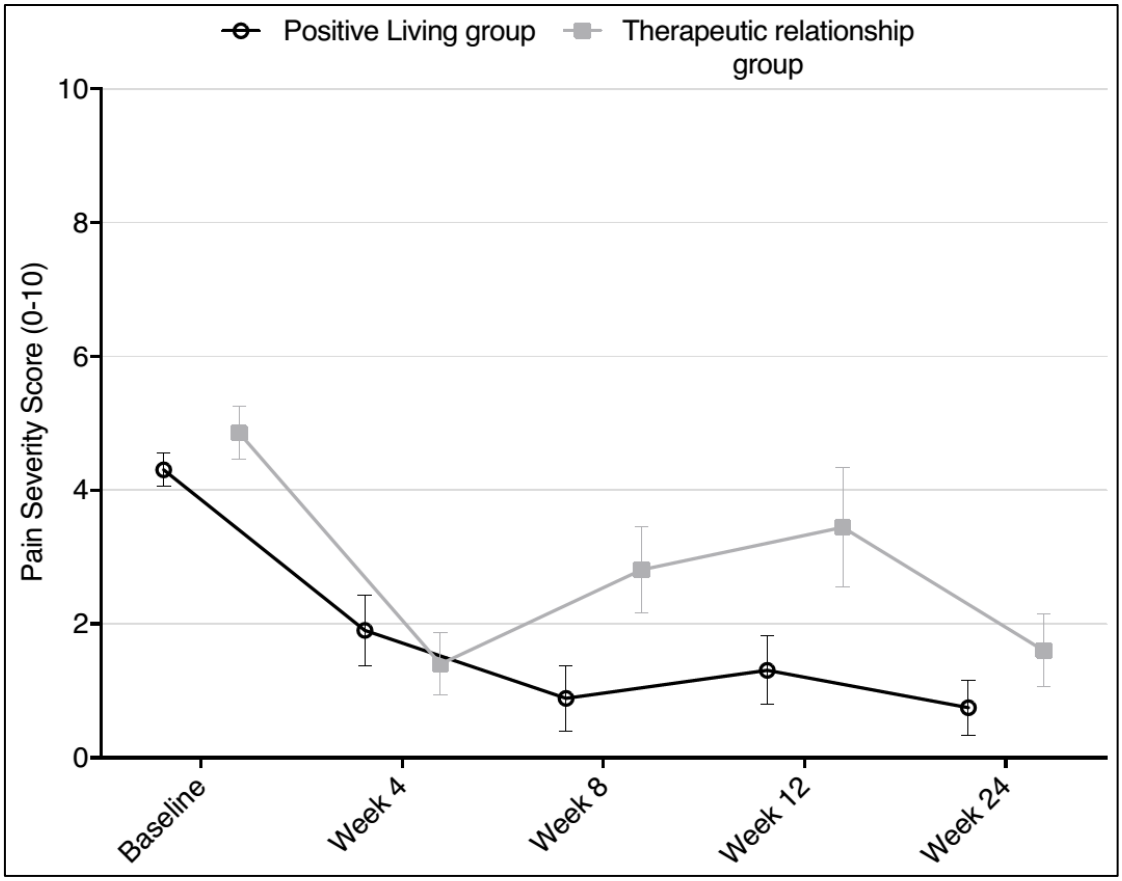

Figure 4-7: Change in Pain Severity Scores for PL and TR intervention groups over time

Table 4-7: PSS for participants and PL and TR intervention groups at each time point (N = 49)

	Participants	**Positive Living intervention group**	**Therapeutic relationship intervention group**
	Mean ± SD (Range)	Mean ± SD (Range)	Mean ± SD (Range)
Baseline	N = 49	n = 26	n = 23
PSS	4.57 ± 1.59 (2-9.5)	4.31 ± 1.25 (2-6.25)	4.86 ± 1.89 (2-9.5)
Week 4	N = 32	n = 19	n = 13
PSS	1.7 ± 2.05 (0 - 7.75)	1.91 ± 2.23 (0 - 7.75)	1.4 ± 1.68 (0 - 4.5)
Week 8	N = 35	n = 15	n = 20
PSS	2.05 ± 2.61 (0 -9)	1.03 ± 1.84 (0 – 5.5)	2.81 ± 2.88 (0 - 9)
Week 12	N = 32	n = 18	n = 14
PSS	2.26 ± 2.85 (0 - 10)	1.33 ± 2.05 (0 – 5.5)	3.45 ± 3.35 (0 - 10)
Week 24	N = 27	n = 15	n = 12
PSS	1.13 ± 1.75 (0 - 5.25)	0.75 ± 1.57 (0 – 4.75)	1.6 ± 1.89 (0 - 5.25)

Successful pain management, for which a clinically important reduction in pain severity is necessary, is regarded as a reduction of three points on a scale of 0-10[263]. There was no significant difference between groups in the number of participants having successful reduction in pain severity (Table 4-8). The percentage of participants with successful reduction in pain was 52% at Week 4 for the PL intervention group and by Week 8, after the completion of the PL programme, the percentage of participants with successful reduction in pain was 67%. Over the next two data collection points, Weeks 12 and 24, the percentage of participants with successful reduction in pain remained at 67%. The percentage of participants with successful reduction in pain at Week 4 for the TR intervention group was 77%, which then reduced to 45% by Week 8 and then reduced further at Week 12, when 36% of participants were found to have a successful reduction in pain. By Week 24 the percentage of participants in the TR intervention group with successful reduction in pain had improved to 67%, the same percentage which was found in the PL intervention group. This indicates that there was no difference in the efficacy of the PL programme and the TR intervention combined compared to the TR intervention alone, to bring about clinically meaningful changes in PSS. This finding is supported by the results of the mixed model regression analysis on PSS.

Table 4-8: Success of PL and TR intervention groups for change in PSS (N = 49)

	Participants	**Positive Living intervention group**	**Therapeutic relationship intervention group**		
	Number	Number	Number	Odds Ratio	Significance test
Baseline - Week 4	N = 32	n = 19	n = 13	0.33	$\chi^2 = 1.94$; p = 0.16
Successful*	20	10	10		
Not successful	12	9	3		
Baseline - Week 8	N= 35	n = 15	n = 20	2.44	$\chi^2 = 1.62$; p = 0.2
Successful	19	10	9		
Not successful	16	5	11		
Baseline - Week 12	N= 32	n = 18	n = 14	3.6	$\chi^2 = 3.03$; p = 0.8
Successful	17	12	5		
Not successful	15	6	9		
Baseline - Week 24	N= 27	n = 15	n = 12	1	$\chi^2 = 0$; p = 1
Successful	18	10	8		
Not successful	9	5	4		

*Successful represents a decrease in PSS of ≥ 3/10[224,258].

4.4.4 Pain Interference Scores

The change in PIS over time is presented in Figure 4-8 and PIS at each time point are presented in Table 4-9. There was no significant difference between groups for Pain Interference Scores (PIS) at Baseline ($t = 1.19$; $p = 0.24$) (Table 4-9). A cumulative linked mixed-model ordinal regression was used to analyse change in PIS over time. In comparison with the null model, the models for the effect of time, group and time, and group and time with random intercepts and slope were significantly better. These models remained significant after correction, and the best model included time and group with random intercepts and slopes when compared with each other. Time was found to be an independent predictor of PIS over the 24 weeks of the study ($p < 0.001$), but group, and group and time interaction had no significant effect on PIS. Therefore, PIS reduced significantly over time in both groups, while receiving the therapeutic relationship.

There is anecdotal evidence to indicate that a reduction in PIS ranging between one and three represents a clinically meaningful change in pain interference on the BPI[224]. As the PIS of both intervention groups reduced by more than three points, these results can be therefore be considered as clinically important changes in pain interference according to the IMMPACT recommendations in a study by Dworkin and colleagues[224].

One participant who was present at Baseline data collection did not complete the PIS section of the BPI questionnaire. Therefore the results on PIS represent one less participant (from the TR intervention group) than Figure 4-2 (p.106) reports.

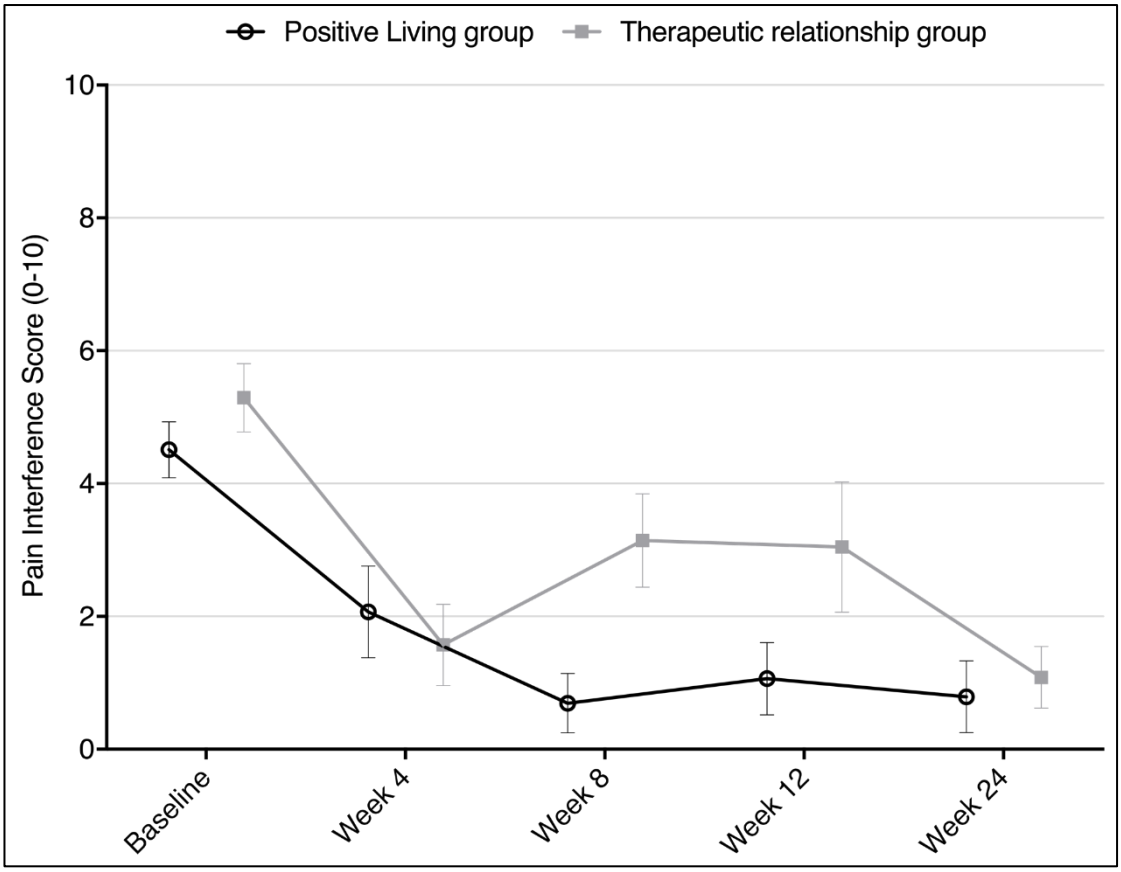

Figure 4-8: Change in Pain Interference Scores for PL and TR intervention groups over time

Table 4-9: PIS for participants and PL and TR intervention groups at each time point (N = 49)

	Participants	**Positive Living intervention group**	**Therapeutic relationship intervention group**
	Mean ± SD (Range)	Mean ± SD (Range)	Mean ± SD (Range)
Baseline	N = 48	n = 26	n = 22
PIS	4.87 ± 2.28 (0.29 – 9.71)	4.51 ± 2.15 (0.29 – 8.43)	5.29 ± 2.41 (0.43 – 9.71)
Week 4	N = 32	n = 19	n = 13
PIS	1.87 ± 2.68 (0 - 9)	2.07 ± 3.01 (0–9)	1.57 ± 2.21 (0 – 6)
Week 8	N = 35	n = 15	n = 20
PIS	2.21 ± 2.89 (0 - 8.43)	0.87 ± 1.74 (0 - 5.29)	3.21 ± 3.19 (0 – 8.4)
Week 12	N = 32	n = 19	n = 13
PIS	1.88 ± 2.95 (0 - 9.86)	1.09 ± 2.25 (0 - 7.14)	3.04 ± 3.53 (0 – 9.86)
Week 24	N = 27	n = 15	n = 12
PIS	0.92 ± 1.86 (0 - 7.14)	0.79 ± 2.09 (0-7.14)	1.08 ± 1.6 (0 – 4.71)

4.4.5 Pain Management Index (PMI)

There was no significant difference for PMI scores between the PL intervention group (-0.69 ± 0.47) and the TR intervention group (-0.95 ± 0.58) at Baseline ($t = -1.7$; $p = 0.09$). The mean PMI score for the sample at Baseline was -0.81 (± 0.53), indicating inadequate pain management in both groups. PMI was analysed using a cumulative link mixed-model ordinal regression. All models were significant compared with the null model and after correction for multiple comparisons. The best model, when the four models were compared, included the effect of group and time with random intercepts and slopes. In this model, there was a significant effect of time over the 24 weeks of the study ($p < 0.001$) as the PMI score improved over time in participants regardless of group. There was no significant effect of group or group and time interaction. The change in PMI over time is presented in Figure 4-9, and indicates adequate management by Week 24 in both groups. Therefore, the PL and TR intervention groups had significantly better pain management over time, according to the PMI score.

It is noteworthy that no change in participants' analgesic prescription was reported over the study period by any participant. The change in PMI presented in Figure 4-9 is therefore as a result of change in pain severity.

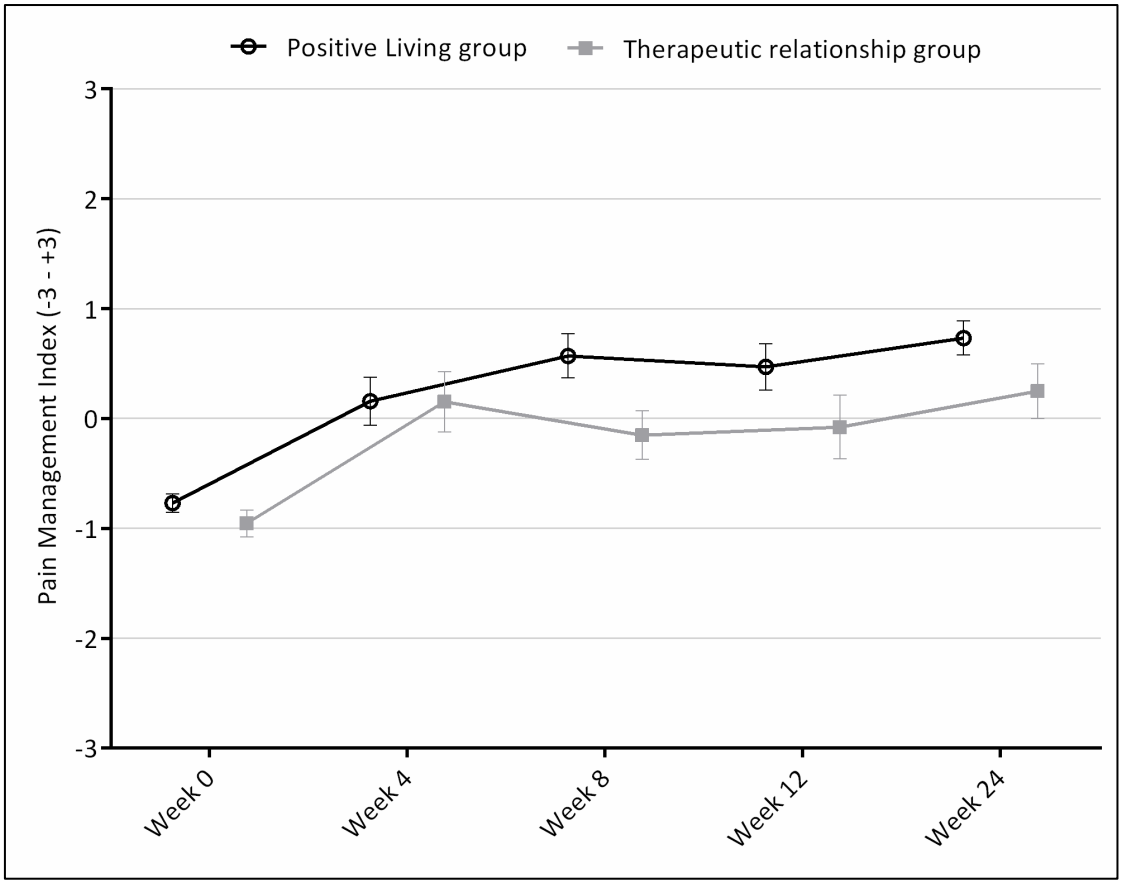

Figure 4-9: Change in Pain Management Index for PL and TR groups over time

4.5 Change in symptoms of depression

No significant differences were found between groups for the scores on the BDI at Baseline ($t = 1.3$; $p = 0.2$). The mean scores at Baseline on the BDI for the sample, PL intervention group and TR intervention group were 25.73 (± 11.2), 23.8 (± 9.9) and 27.91 (± 12.21) respectively. A linear mixed-model regression was used to analyse the BDI scores. Data were transformed using a square root as data were not normally distributed initially and were right skewed. All models were significant when compared with the null model and after correction for multiple comparisons. Once comparisons were made between the models, no model was better than another. Therefore, the simplest model was chosen, which included the effect of time ($p < 0.001$). In this chosen best model, there was no significant effect of group, or group and time. There was a significant inverse relationship which existed between time and BDI score over the 24 weeks of the study. The results show that the BDI in both groups significantly improved over time and had few symptoms of depression by Week 24. The change in BDI scores over time are presented in Figure 4-10.

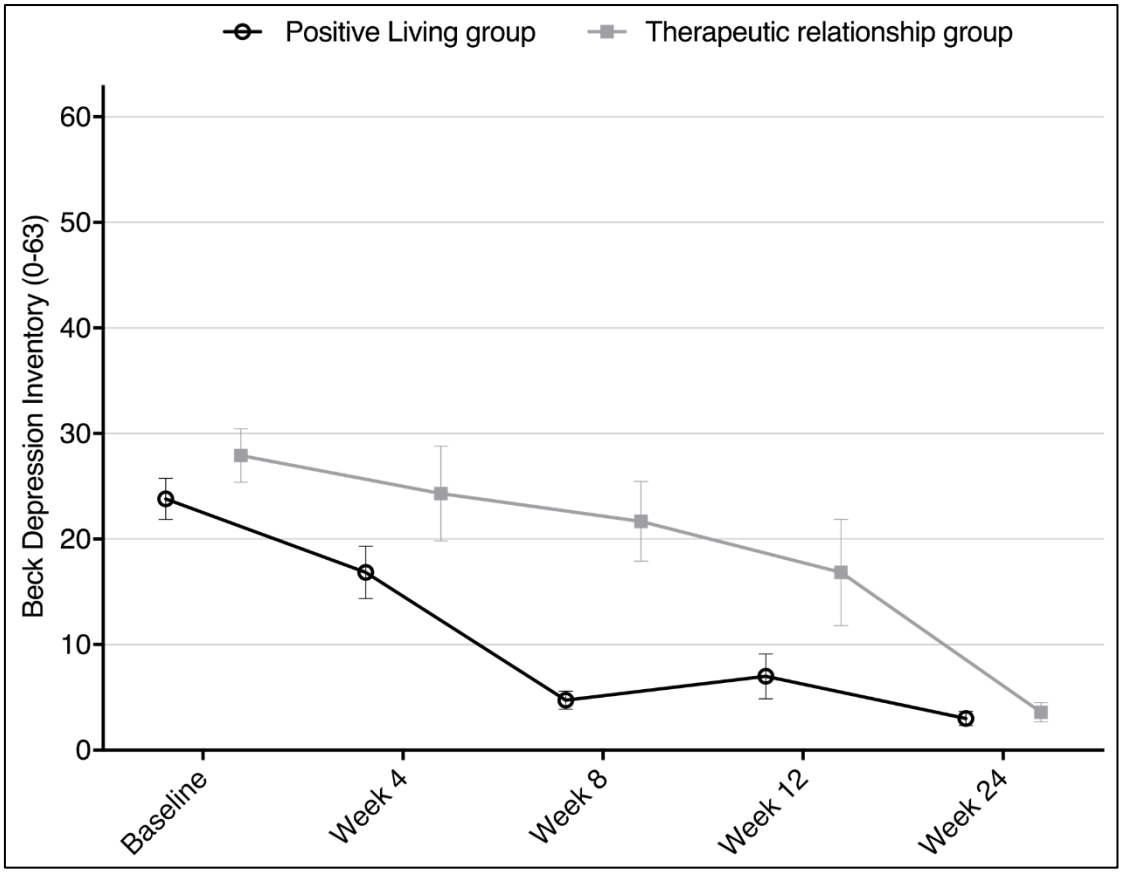

Figure 4-10: Change in scores on the Beck Depression Inventory over time

4.6 Change in health-related quality of life

The PL intervention group scored significantly higher than the TR intervention group on HRQoL, measured by the EQ-5D VAS ($t = 3.38$; $p < 0.01$) and EQ-5D Index ($t = 3.2$; $p < 0.01$) at Baseline (Table 4-10). Figure 4-11 and Figure 4-12 show the changes over time for EQ-5D VAS and EQ-5D Index respectively.

Table 4-10: EQ-5D VAS and EQ-5D Index scores at Baseline (N = 49)

	Participants	**Positive Living intervention group**	**Therapeutic relationship intervention group**	
	Mean ± SD (Range)	Mean ± SD (Range)	Mean ± SD (Range)	Significance test
Baseline	N = 49	n = 26	n = 23	
EQ-5D VAS	59.9 ± 16.6 (20 – 90)	66.73 ± 15.03 (40 – 90)	52.17 ± 15.06 (20 – 80)	t = 3.38; p < 0.01*
EQ-5D Index	0.6 ± 0.28 (-0.32 – 0.8)	0.71 ± 0.14 (0.09 – 0.8)	0.47 ± 0.34 (-0.32 – 0.8)	t = 3.2; p < 0.01*

*Indicates a significant difference between groups

4.6.1 EQ-5D VAS

Data for the EQ-5D VAS were processed by dividing it into proportions before regression was performed. Following an initial attempt of a linear mixed-model regression to model the data, a general additive mixed-model (model with inflated beta distribution) (GAMLSS) was used for analysis.

The models for the effect of group, time, group and time converged and comparisons were made using a likelihood ratio test for the nested GAMLSS model, for which the effect of time, and group and time were significant. After stepwise removal of terms, the best model included time. For the EQ-5D VAS there was a significant improvement over time during the 24 weeks of the study ($p < 0.001$). No effect of group or group and time interaction was found. Therefore, the EQ-5D VAS improved in both intervention groups.

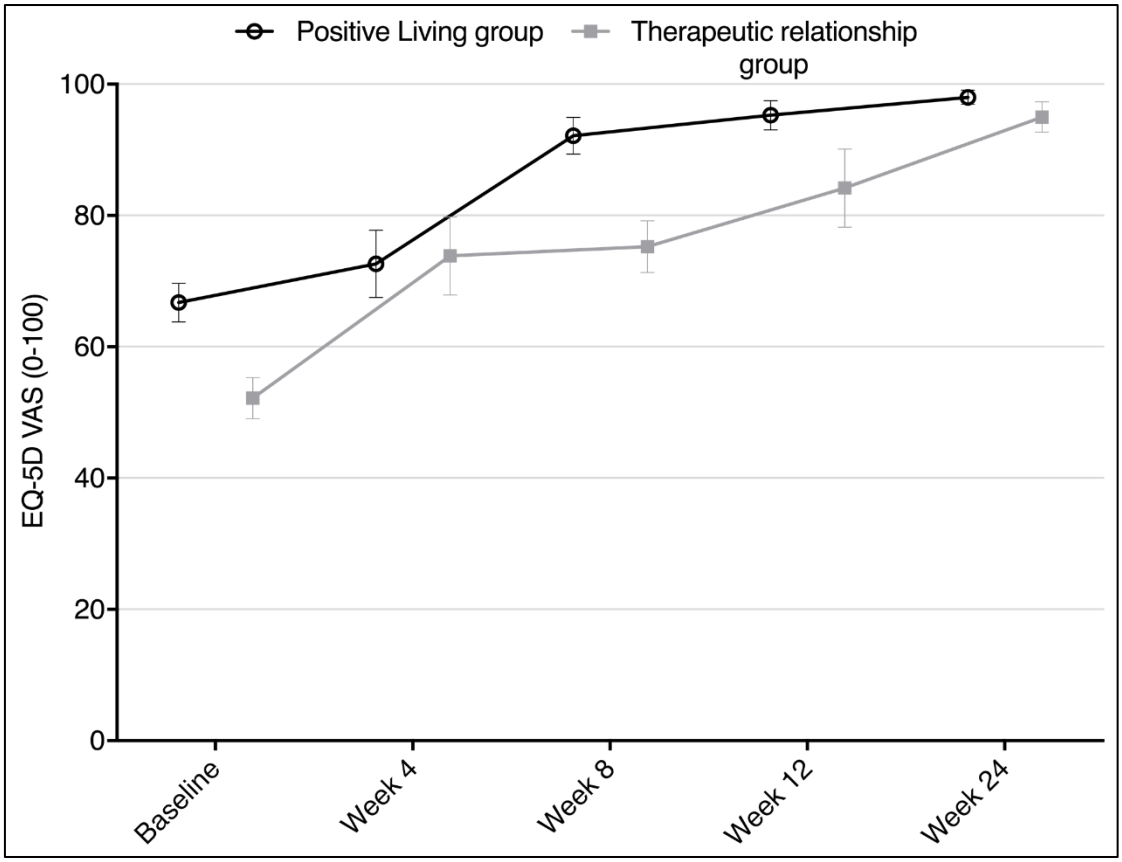

Figure 4-11: Change in EQ-5D VAS scores over time

4.6.2 EQ-5D Index

For the EQ-5D Index, data could not be modelled using mixed-model regression. An appropriate model could not be generated using GAMLSS. The analysis was therefore done using t-tests and a one-way ANOVA.

There were significant differences between groups for the EQ-5D Index at Baseline (t = 3.32; p < 0.01) and Week 8 (t = 2.86; p < 0.01) (Table 4-11), where the PL intervention group had better EQ-5D Index scores than the TR intervention group. No significant differences between groups were found at Week 24 (t = 1.27; p = 0.22) (Table 4-11). Over the 24 weeks of the study, the EQ-5D Index scores of the participants improved significantly ($F_{(4-48)}$ = 13.84; p < 0.001) (Figure 4-12), indicating improvement in HRQoL.

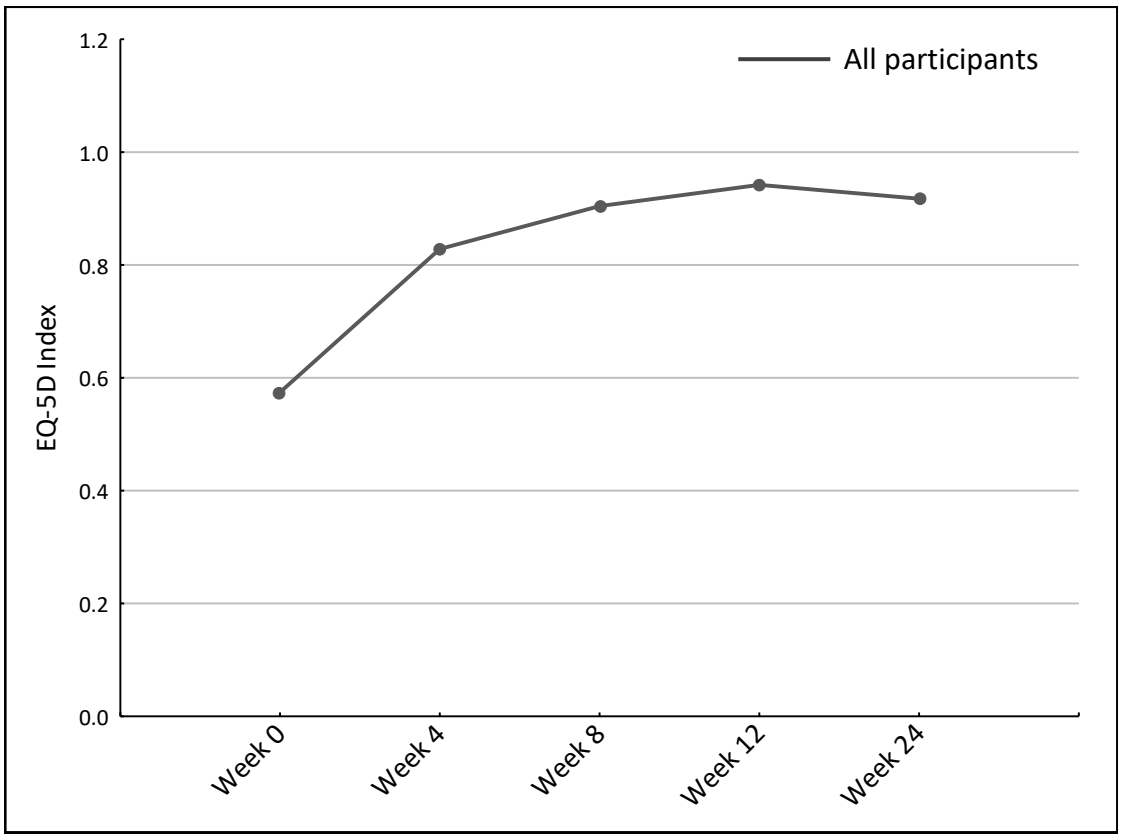

Figure 4-12: Change in EQ-5D Index scores over time

Table 4-11: EQ-5D Index scores for PL and TR intervention groups over time (N = 49)

	Participants	**Positive Living intervention group**	**Therapeutic relationship intervention group**	
	Mean ± SD (Range)	Mean ± SD (Range)	Mean ± SD (Range)	Significance test
Baseline	N = 49	n = 26	n = 23	t = 3.32; p < 0.01*
EQ-5D Index	0.6 ± 0.28 (-0.32 - 0.8)	0.71 ± 0.14 (0.01 - 0.8)	0.47 ± 0.34 (-0.32 - 0.8)	
Week 4	N = 32	n = 19	n = 13	t = 1.08.5; p = 0.29
EQ-5D Index	0.75 ± 0.28 (-0.14 - 1)	0.8 ± 0.26 (-0.14 - 1)	0.69 ± 0.31 (-0.2 - 1)	
Week 8	N = 34	n = 15	n = 19	t = 2.86; p < 0.01*
EQ-5D Index	0.78 ± 0.3 (-0.38 - 1)	0.93 ± 0.1 (0.76 - 1)	0.66 ± 0.35 (-0.38 - 1)	
Week 12	N = 31	n = 19	n = 12	t = 2.02; p > 0.05
EQ-5D Index	0.84 ± 0.33 (-0.59 - 1)	0.93 ± 0.16 (0.33 - 1)	0.69 ± 0.47 (-0.59 - 1)	
Week 24	N = 27	n = 15	n = 12	t = 1.27; p = 0.22
EQ-5D Index	0.95 ± 0.09 (0.69 - 1)	0.97 ± 0.07 (0.8 - 1)	0.93 ± 0.11 (0.69 - 1)	

* Indicates a significant difference between groups

4.7 Change in self-efficacy

Self-efficacy scores were not significantly different between the groups at Baseline ($t = 0.94$; $p = 0.35$). The mean self-efficacy scores for the sample, PL intervention group and TR intervention group at Baseline were 6.15 (± 2.28), 6.44 (± 1.9) and 5.83 (± 2.65). For analysis of self-efficacy scores, a linear mixed-model regression was performed to test for effect after transforming the data by squaring it, due to it being right skewed. The group, group and time, and group and time with random intercepts and slopes models were significant compared with the null model. After correction, group, group and time, and group and time with random intercepts and slopes remained significant. Comparisons between these models found that the effect of group and time with random intercepts and slopes was the best model. The model showed that regardless of group, the self-efficacy scores in all participants significantly increased over time ($p < 0.001$). The group was also an independent predictor as there was a significant difference between groups ($p < 0.5$), possibly from differences between groups around Week 8, and therefore there may not be a significant difference between groups for self-efficacy at Week 24. There was no significant effect of the group and time interaction, indicating that the intervention groups were improving at similar rates over time. Although, the PL intervention group had significantly better self-efficacy scores than the TR intervention group over the 24 weeks of the study, both groups improved significantly in self-efficacy scores. The change over time for self-efficacy is presented in Figure 4-13.

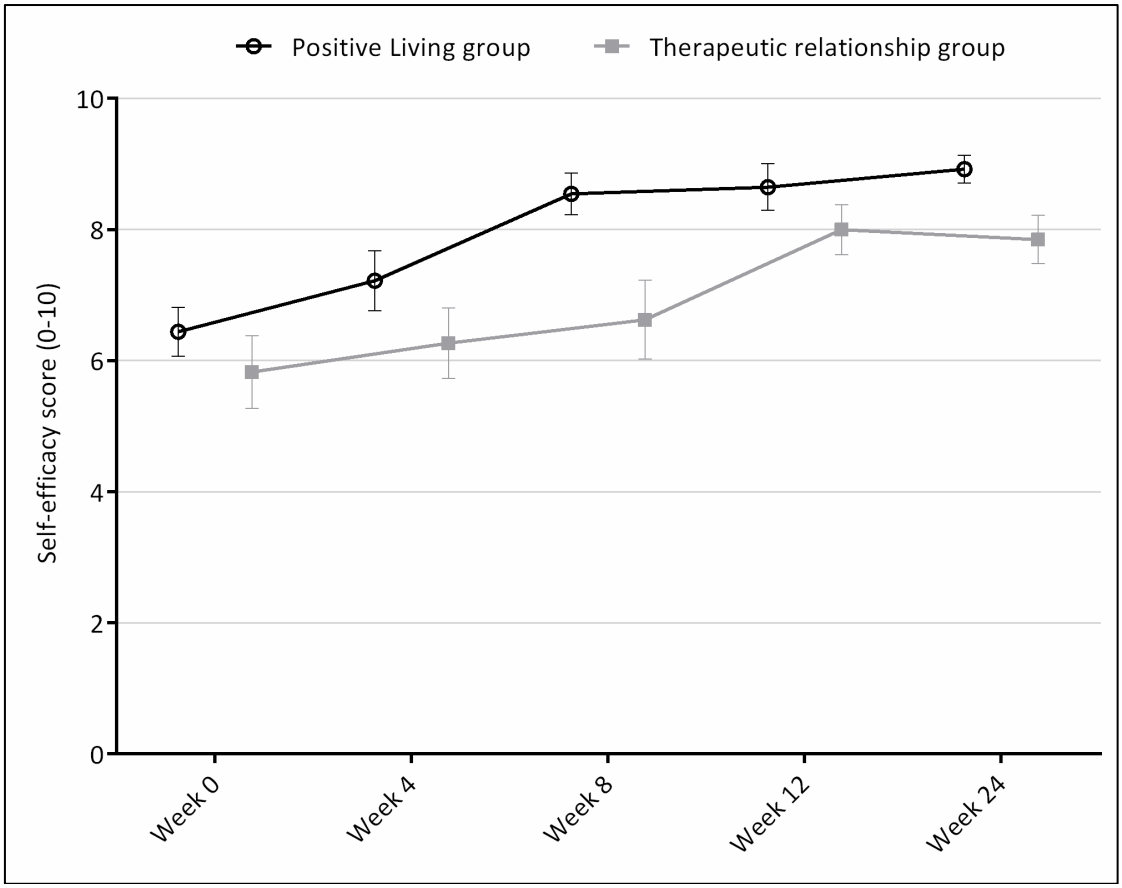

Figure 4-13: Change in self-efficacy scores over time

4.8 Change in function over time

No significant differences were found between the groups for any of the functional tests in the physical performance task battery (PPTB) at Baseline (Table 4-12).

Table 4-12: Performance of the PPTB for PL and TR group at Baseline (N = 49)

	Participants	**Positive Living intervention group**	**Therapeutic relationship intervention group**	
	Mean ± SD (Range)	Mean ± SD (Range)	Mean ± SD (Range)	Significance test
Baseline	N = 45	n = 26	n = 19	
Walking at preferred speed (min)	18.55 ± 3.2 (14.09 – 28.66)	18.96 ± 3.49 (14.09 – 28.66)	17.97 ± 2.8 (14.43 – 24.59)	t = 1.02; p = 0.32
Walking at fastest speed (min)	12.48 ± 2.1 (8.78 – 18.25)	12.53 ± 2.38 (8.78 – 18.25)	12.41 ± 1.72 (8.78 – 15.22)	t = 0.19; p = 0.85
6-minute walk (m)	357.19 ± 74.79 (90 - 466)	352.25 ± 80.05 (90 – 465)	363.95 ± 68.48 (188.5 – 466)	t = 0.51; p = 0.61
	N = 49	n = 26	n = 23	
Unloaded forward reach (cm)	107.82 ± 9.11 (81 – 125)	107.88 ± 9.79 (81 – 125)	107.74 ± 8.49 (90 – 123)	t = 0.06; p = 0.96
Loaded forward reach (cm)	88.63 ± 10.58 (65-120)	88.5 ± 10.71 (65 – 120)	88.78 ± 10.66 (68 – 109)	t = 0.09; p = 0.93
	N = 48	n = 26	n = 22	
Timed, repeat sit-to-stand (s)	5.92 ± 1.35 (3.81 – 10.81)	5.92 ± 1.26 (3.81 – 8.82)	5.91 ± 1.49 (4.21 – 10.81)	t = 0.01; p = 0.99
Timed, repeated reach-up (s)	4.25 ± 1.41 (2.09 – 9.31)	3.89 ± 1.48 (2.09 – 9.31)	4.68 ± 1.21 (3.14 – 7.59)	t = 2.01; p > 0.05
Timed belt-tie (s)	5.5 ± 1.72 (3.15 – 9.54)	5.19 ± 1.58 (3.15 – 9.22)	5.87 ± 1.84 (3.5 – 9.54)	t = 1.38; p = 0.17

4.8.1 Walking at preferred speed, walking at fastest speed, six-minute walk test

Changes in speed over time for the walking at preferred speed and walking at fastest speed are presented in Figure 4-14 and Figure 4-15 respectively. There was no reason to do mixed-model analysis as the graphical presentation of data indicated no clear changes across time or between groups. Four participants from the TR intervention group chose not to walk at Baseline and therefore were not represented in the tests which included walking (Figure 4-2; p.106).

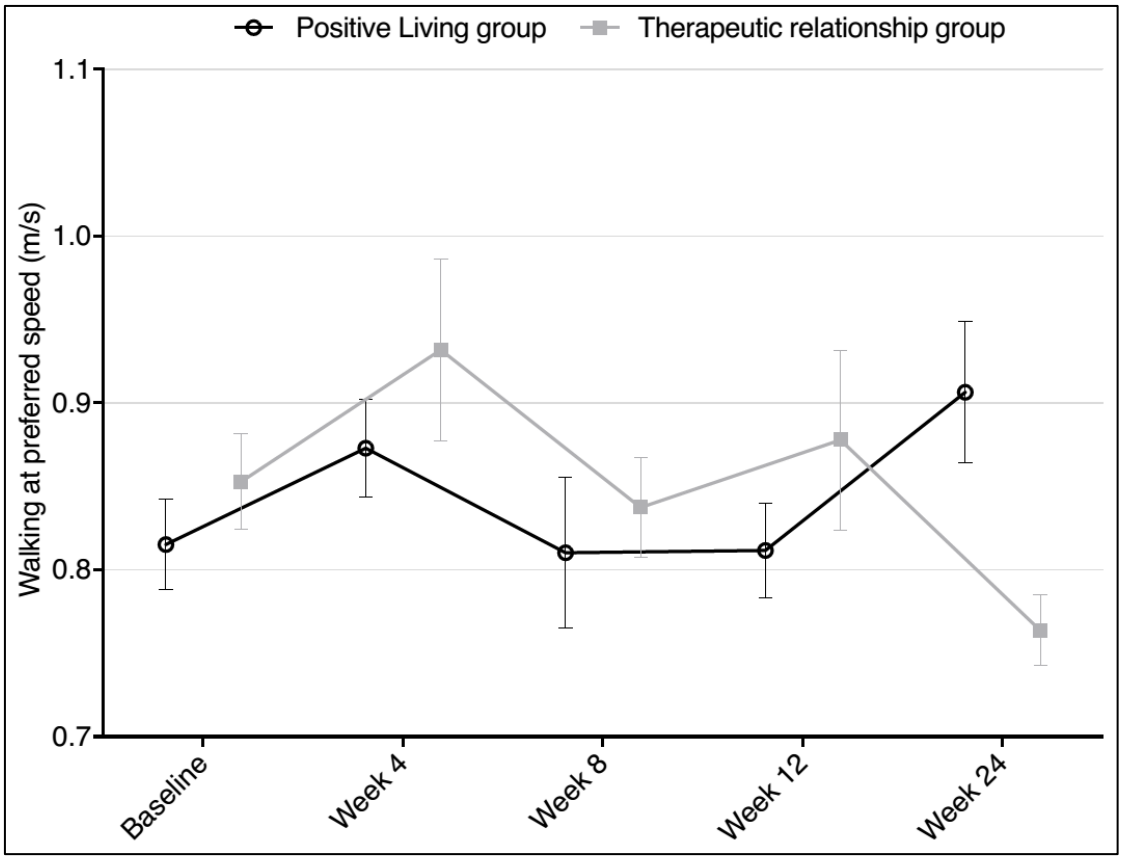

Figure 4-14: Change in speed in walking at preferred speed test

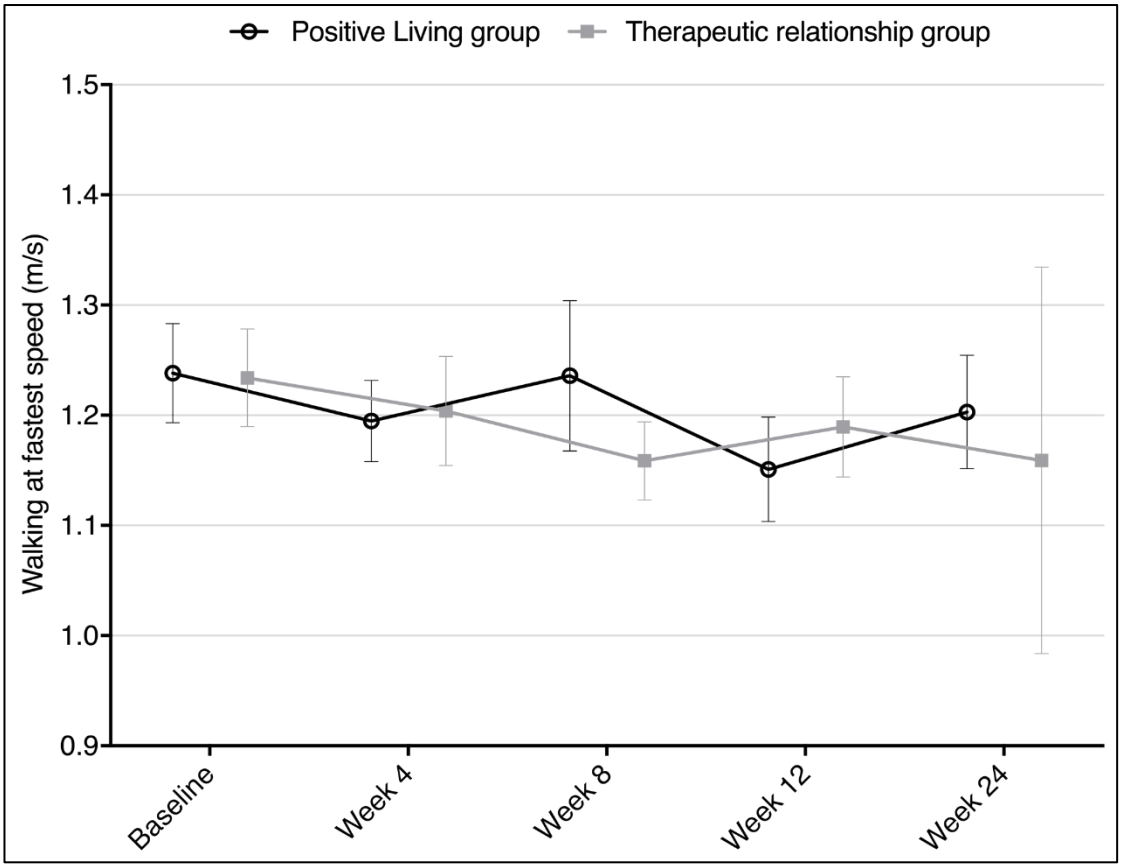

Figure 4-15: Change in speed over time in walking at fastest speed test

For the six-minute walk test (6MWT), Figure 4-16 presents the changes in distance over time. Analysis on the 6MWT was done using a linear mixed-model regression on data transformed by squaring due to left-skewed data. Compared with the null model, models for the effect of time, group and time and group and time with random intercepts and slopes were significant. After family-wise p-value correction the models for the effect of time, and group and time remained significant. There was no significant difference between the models, resulting in the simplest model being chosen as the best model, which included time. There was a positive significant relationship between time and six-minute walk distance (6MWD) over the 24 weeks of the study ($p < 0.001$). No significant difference existed between groups and there was no significant effect of the group and time interaction according to this model. Therefore, over the 24 weeks of the study there was a significant increase in the distance walked in six minutes in both intervention groups, indicating that both groups improved over time.

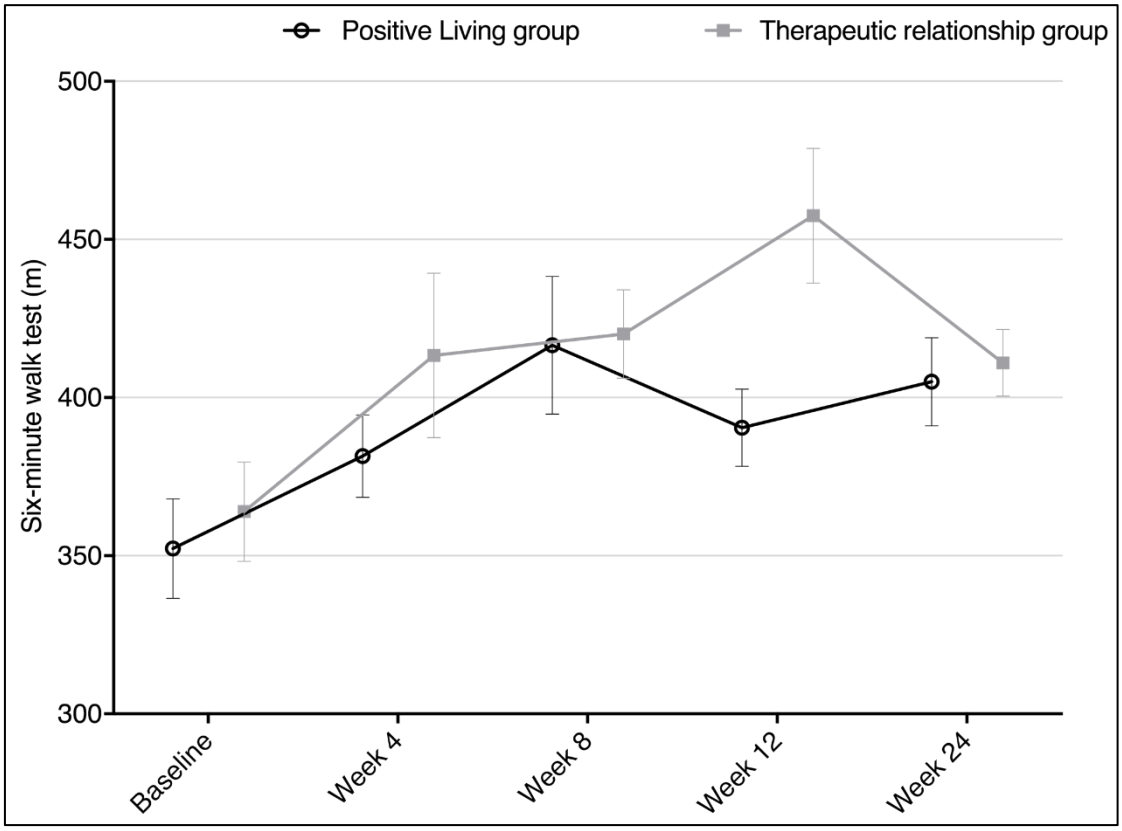

Figure 4-16: Change in six-minute walking distance over time

4.8.2 Unloaded and loaded forward reach tests

Change in distance over time in the unloaded and loaded forward reach tests are presented in Figure 4-17 and Figure 4-18. A linear mixed model regression was done to analyse the distance over time of the unloaded forward reach test. Models, which included the effect of time, group and time, and group and time with random intercepts and slopes were significant compared with the null model and remained significant with correction for multiple comparisons. As no significant differences were found in comparing the models, the best model included the effect of time, as it was the simplest model. This model found a significant positive relationship between time and distance of the unloaded reach test ($p < 0.001$). There was no effect of group or group and time interaction found in this model. Both intervention groups were able to reach further over the 24 weeks of the study, however there was no difference between the groups in the distance reached.

The analysis of the loaded forward reach test had the same findings. There was a significant positive relationship between time and distance of the loaded reach test ($p < 0.001$). No effect of group or group and time interaction existed in this model. Therefore, both groups were able to reach further, whilst holding a weight, over the 24 weeks of the study.

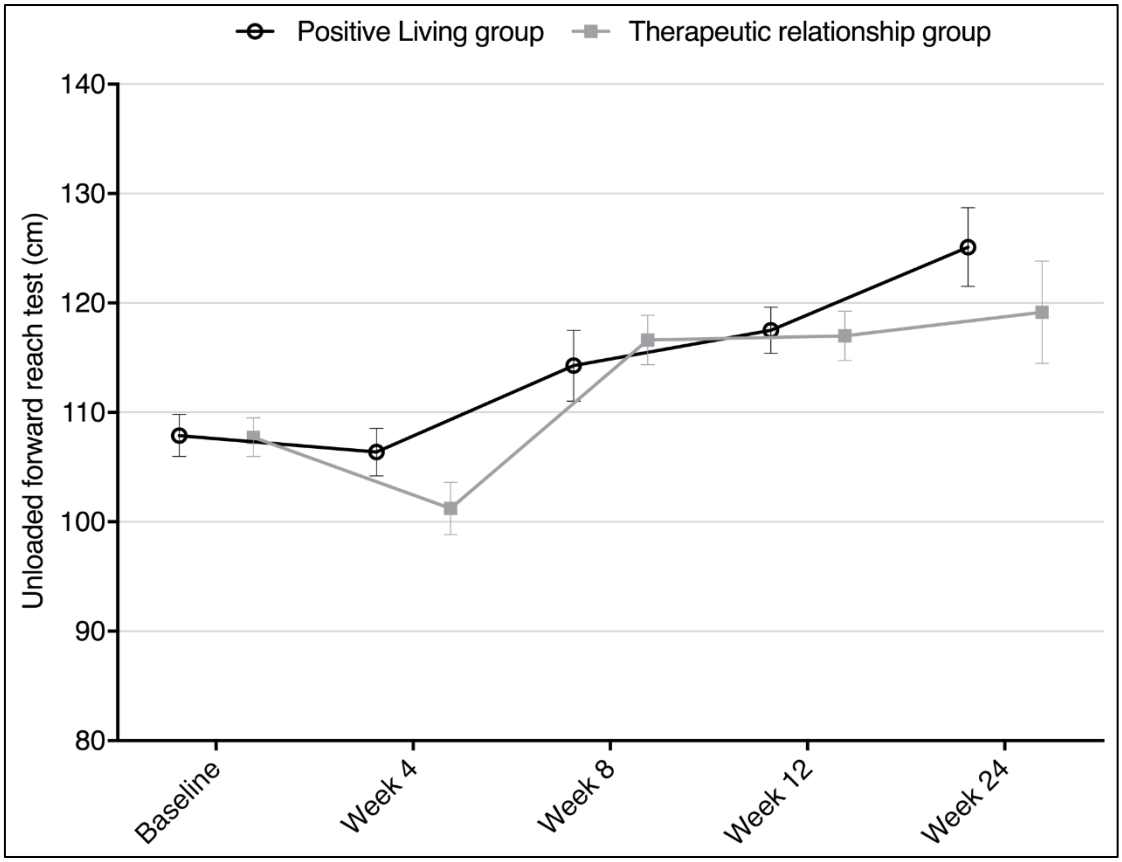

Figure 4-17: Change in distance over time for unloaded forward reach

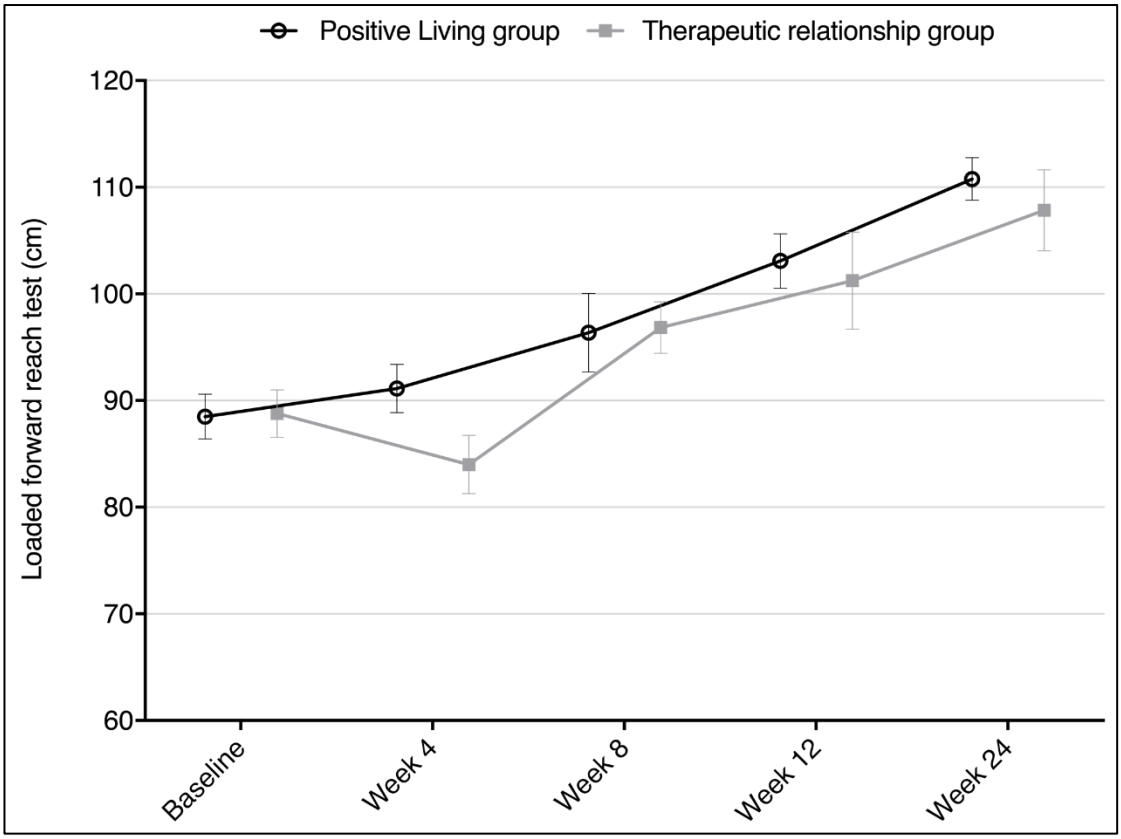

Figure 4-18: Change in distance over time for loaded forward reach test

4.8.3 Timed repeated sit-to-stand, repeated reach-up and belt-tie tests

Attempts to model the data for the timed, repeated sit-to-stand, repeated reach-up and belt-tie tests failed. Therefore, regression analysis was not used for these tests. Changes over time, analysed by one-way ANOVA tests, are presented in Figure 4-19 for the timed, repeated sit-to-stand test, Figure 4-20 for the timed, repeated reach-up test and Figure 4-21 for the timed belt tie test.

There were no differences, analysed by t-tests, between groups at Week 24 (Table 4-13) for any of the three timed tests. A significant difference between groups was found for the timed, repeated reach-up test at Week 8 ($t = 2.6$; $p = 0.02$) (Table 4-13). For the participants (both intervention groups) there was a significant effect of time, over the 24 weeks of the study, for the timed, repeated sit-to-stand test ($F_{(4\text{-}28)} = 19.19$; $p < 0.001$), the timed, repeated reach-up test ($F_{(4\text{-}32)} = 15.23$; $p < 0.001$) and timed belt tie test ($F_{(4\text{-}28)} = 7.01$; $p < 0.01$). The results indicated that the time taken for performing these three tests decreased over the 24 weeks of the study, meaning that both groups showed improvement in their timed performance of these tasks. One participant from the TR intervention group chose not to do any of the timed-tests at Baseline and therefore the change in timed-tests represent one less participant than was present at data collection (Figure 4-2; p.106).

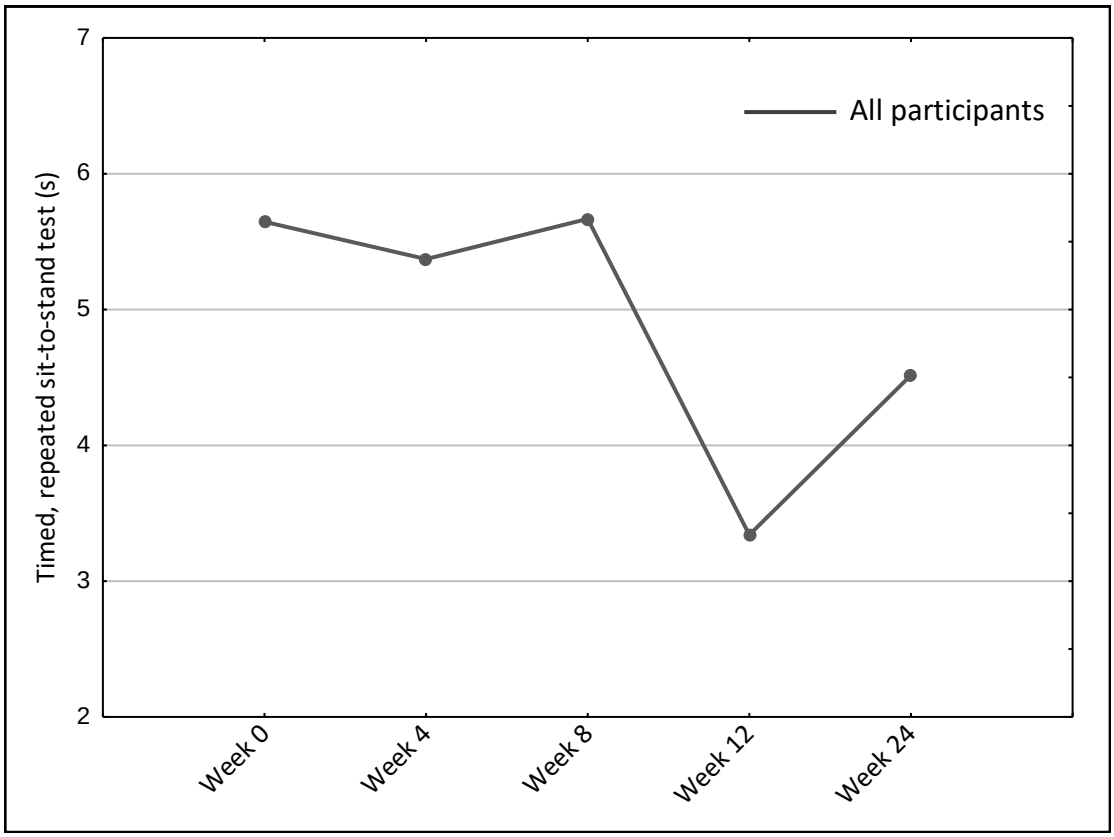

Figure 4-19: Change in seconds over time for timed, repeated sit-to-stand test

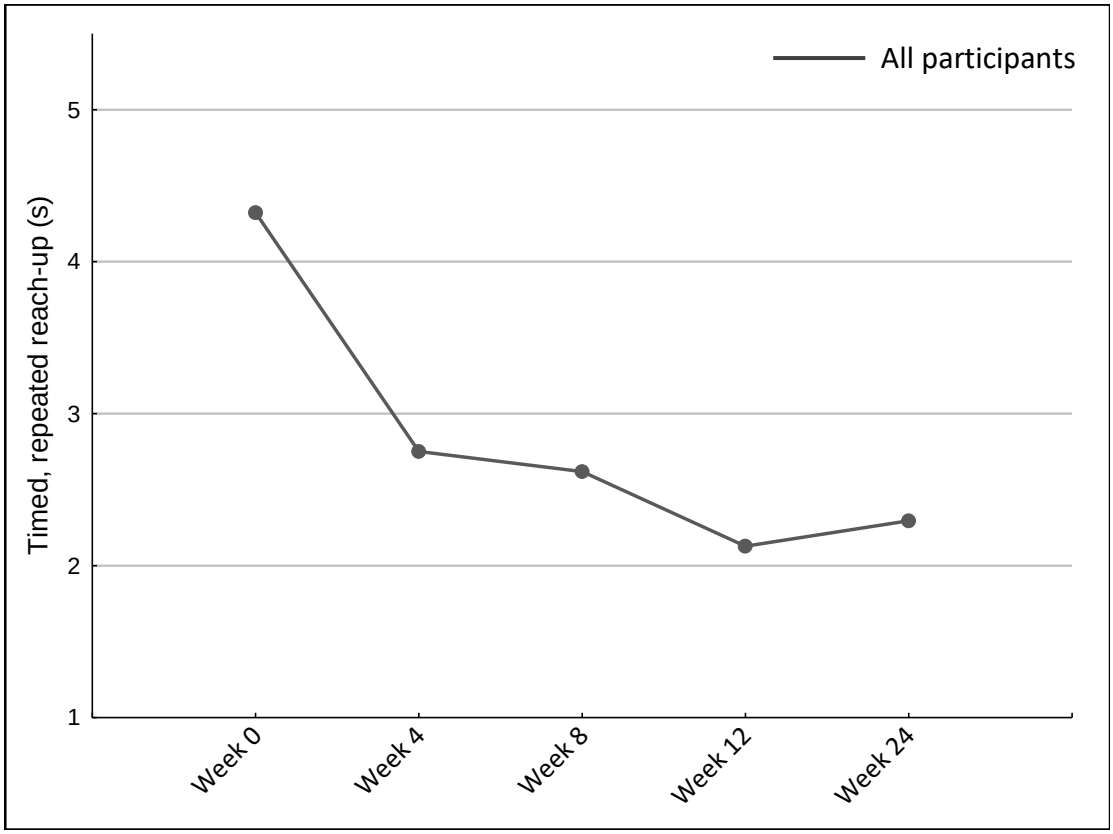

Figure 4-20: Change in seconds over time for timed, repeat reach-up test

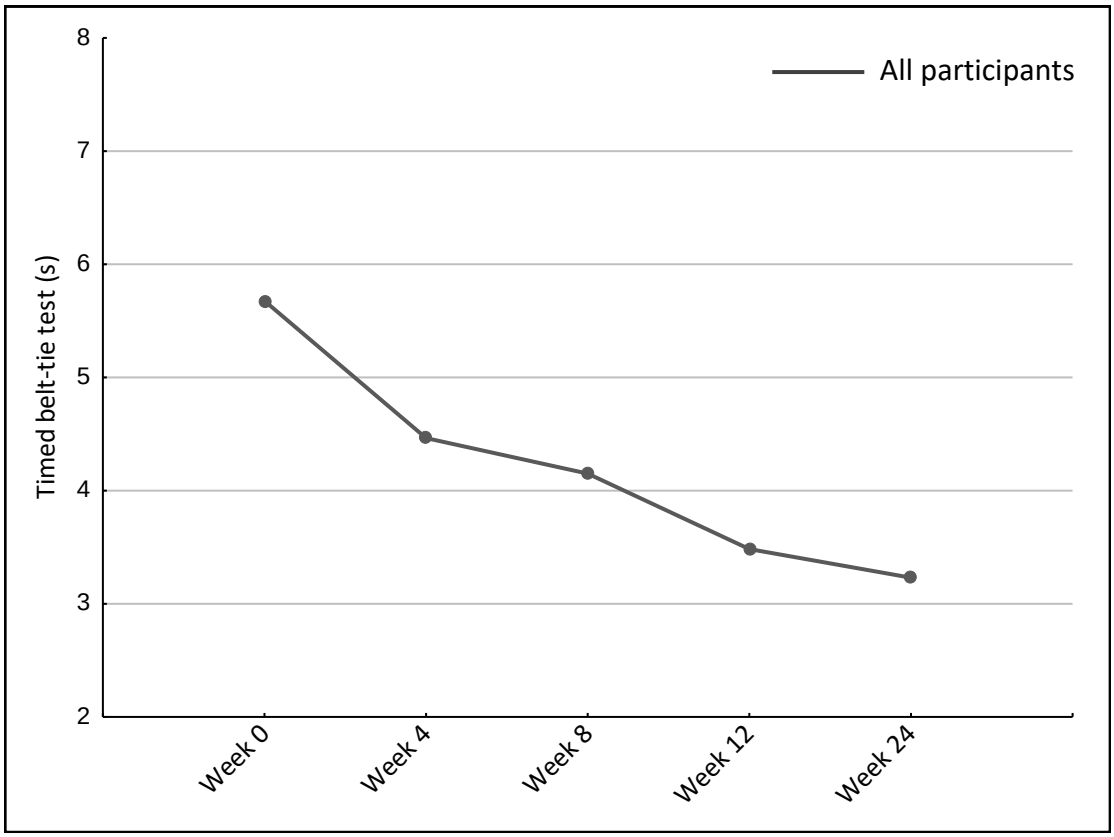

Figure 4-21: Change in seconds over time for timed belt-tie test

Table 4-13: Performance of timed tests of the PPTB for PL and TR group over time (N = 49)

	Participants	**Positive Living intervention group**	**Therapeutic relationship intervention group**	
	Mean ± SD (Range)	Mean ± SD (Range)	Mean ± SD (Range)	Significance test
Baseline	N = 48	n = 26	n = 22	
Timed, repeat sit-to-stand (s)	5.92 ± 1.35 (3.81 – 10.81)	5.92 ± 1.26 (3.81 – 8.82)	5.91 ± 1.49 (10.81 – 1.62)	t = 0.01; p = 0.99
Timed, repeated reach-up (s)	4.25 ± 1.41 (209 – 9.31)	3.89 ± 1.48 (2.09 – 9.31)	4.68 ± 1.21 (3.14 – 7.59)	t = 2.01; p > 0.05
Timed belt-tie (s)	5.5 ± 1.7 (3.15 – 9.54)	5.19 ± 1.58 (3.15 – 9.22)	5.87 ± 1.84 (3.5 – 9.54)	t = -1.38; p = 0.17
Week 4	N = 24	n = 16	n = 8	
Timed, repeat sit-to-stand (s)	5.67 ± 1.32 (3.49 – 8.91)	5.83 ± 1.33 (3.87 – 8.91)	5.4 ± 1.33 (3.49 – 7.92)	t = 0.73; p = 0.47
	N = 25	n = 16	n = 9	
Timed, repeated reach-up (s)	2.89 ± 0.93 (1.87 – 6.17)	2.89 ± 1.07 (1.87 – 6.17)	4.68 ± 1.21 (2.09 – 3.87)	t = 0.02; p = 0.98
	N = 24	n = 15	n = 9	
Timed belt-tie (s)	4.86 ± 1.1 (2.31 – 7.44)	5.04 ± 0.99 (3.47 – 7.44)	4.55 ± 1.26 (2.31 – 6.71)	t = 1.06; p = 0.3
Week 8	N = 24	n = 11	n = 13	
Timed, repeat sit-to-stand (s)	5.42 ± 1.02 (3.63 – 7.47)	5.45 ± 1.02 (3.74 – 6.96)	5.39 ± 1.05 (3.63 – 7.47)	t = 0.13; p = 0.9
Timed, repeated reach-up (s)	2.56 ± 0.55 (1.69 – 3.49)	2.27 ± 0.37 (1.69 – 2.8)	2.8 ± 0.58 (1.91 – 3.49)	t = 2.6; p = 0.02*
Timed belt-tie (s)	4.37 ± 1.03 (2.7 – 6.96)	4.29 ± 1.12 (2.7 ± 6.59)	4.44 ± 0.98 (3.17 – 6.96)	t =-0.35; p = 0.73
Week 12	N = 21	n = 12	n = 9	
Timed, repeat sit-to-stand (s)	3.32 ± 0.6 (1.71 – 4.71)	3.43 ± 0.32 (3.04 – 4.1)	3.17 ± 0.85 (1.71 – 4.71)	t = 0.98; p = 0.34
Timed, repeated reach-up (s)	2.26 ± 0.4 (1.54 – 3.26)	2.36 ± 0.39 (1.88 – 3.26)	2.14 ± 0.39 (1.54 – 2.71)	t = 1.28; p = 0.22
Timed belt-tie (s)	3.44 ± 0.52 (2.45 – 4.72)	3.61 ± 0.47 (3.15 – 4.55)	3.2 ± 0.36 (2.45 - 3.71)	t = 1.91; p = 0.07

	Participants	Positive Living intervention group	Therapeutic relationship intervention group	
	Mean ± SD (Range)	Mean ± SD (Range)	Mean ± SD (Range)	Significance test
Timed, repeat sit-to-stand (s)	4.49 ± 0.57 (3.36 – 5.47)	4.64 ± 0.49 (3.93– 5.47)	4.27 ± 0.65 (3.36 – 5.38)	t = 1.25; p = 0.23
Timed, repeated reach-up (s)	2.31 ± 0.75 (1.36 – 3.46)	2.41 ± 0.81 (1.36 – 3.44)	2.16 ± 0.7 (1.58 – 3.46)	t = 0.62; p = 0.54
	N = 14	n = 9	n = 5	
Timed belt-tie (s)	3.4 ± 0.65 (2.2 – 4.55)	3.65 ± 0.47 (3.15 – 4.55)	2.94 ± 0.71 (2.2 – 3.82)	t = 2.29; p = 0.4

*Indicates a significant difference between groups

4.9 Participants' responses to post-study structured interviews

The participant responses to the series of open-ended questions, which were asked to participants of both intervention groups during a cellular phone call after the final data collection point, are presented here. The responses were analysed for recurring topics, which arose from more than two participants. These topics and the responses which matched them are presented in Table 4-14 and Table 4-15. Twelve participants in the PL intervention group and thirteen participants in the TR intervention group were reached for the post-study structured interviews.

4.9.1 Participants' responses from the Positive Living intervention group

Participants found the sessions of the PL programme and the workbook helpful. Responses were grouped into topics of learning, pain alleviation, exercise and improving wellness (Table 4-14). No suggestions for additional information to be included in the sessions or in the workbook were made. Three participants (participant 30, 36 and 46) expressed satisfaction with the content and comprehensiveness of the PL programme, while three other participants (participant 15, 26 and 34) were unsure if there was more information which should be added.

Many participants read the workbook, however a few participants reported that they did not. Topics of pain alleviation, exercise and improving wellness emerged again in response to questions on the helpfulness of the workbook, as emerged with the usefulness of the PL programme (Table 4-14). There were mixed responses to whether participants shared or discussed the information gained in the PL programme with others. Five participants (participant 2, 6, 9, 26 and 36) expressed that they did not share the information from the PL programme with anyone else, while five participants (participant 3, 5, 15, 30 and 34) did share information from the PL programme in order to support others and share their experience.

In an opportunity to share anything further, many participants had nothing more they wished to voice. Two participants expressed gratitude and a wish for more PLWHA to have opportunity to participate in the PL programme.

Table 4-14: Positive Living intervention group responses (n = 12)

Topic	Question: Did you find the group useful? Please explain.
Pain alleviation	Participant 2: *"Yes, I had a backache and it got better."* Participant 3: *"And when you are doing the exercises you don't feel any pain." AND "…I feel relieved…"* Participant 9: *"Yes, because since I have been going to the group I feel alright, I don't feel any pain."* Participant 26: "*…because there was a pain that I used to feel on my legs but I can't feel it anymore."*
Exercise	Participant 2: "*[What helped the pain] was doing the exercises."* Participant 3: *"Yes, a lot, because we were always doing the exercises. And when you are doing the exercises you don't feel any pain. And when I wake in the morning I do the exercises and I feel relieved."* Participant 6: *"It is interesting because of the exercising we were doing…"* Participant 26: *"Yes, …because of the exercises."* Participant 30: *"Yes, because I was lazy to do the things like going to the river, when I got the exercises I found it easy to go to the river and my life changed."* Participant 34: *"A lot … if I have a headache I must just take a bucket and go to the river. Even if I have pain, I just do the exercises then after I feel better."*
Improving wellness	Participant 15: *"A lot. I felt alright because of the things she said we must do."* Participant 36: *"Yes. Because it made me to stop regretting myself. I felt alright and strong. It made me accept my situation."* Participant 42: *"Yes, it was helpful because when I don't feel well I does the things that she said we must do."* Participant 46: *"Yes, it was helpful a lot. Because when you are doing the exercises you don't feel any stress, you feel happy all the time you always healthy."*

Topic	Question: Did you read the workbook given to you or have somebody read it to you? Please explain.
Learning	Participant 15: *"…teaches us…" AND "the book tells us how to live when you are HIV positive."* Participant 26*: "The book was telling us…"* Participant 30: *"…It teaches us…"*
Pain alleviation	Participant 26: *"…if you suspect anything you go the clinic, example…when you have pain you have to go the nurse and ask for help."* Participant 30: *"…what to do when you have pain behind the neck."*
Exercise	Participant 3: *"It's about the exercises we've been doing in the group."* Participant 9: *"…you have to do the exercises..."*
Improving wellness	Participant 26: *"…if you suspect anything you go the clinic, example when you have non-stop diarrhoea…you have to go the nurse and ask for help."* Participant 30: *"…how to eat and what we should eat…"*

Topic	Question: Did you find the information in the workbook useful? Please explain.
Learning	Participant 5: *"…it gives me important information..."* Participant 9: *"…it shows us exercises…"* Participant 36: *"…there were things that I didn't know that the book taught me."*
Pain alleviation and exercise	Participant 3: *"…I had pain in the legs and in the morning, my legs would be very stiff, but now that we've been doing different exercise the stiffness and the pain got better."* Participant 9: *"…after the exercises I feel relieved."*
Improving wellness	Participant 2: *"…are helpful for example when you are sick. I used to feel tired all the time."* Participant 5*: "…how to take care of yourself."* Participant 15: *"…you feel alright emotionally…"* AND *"…after I have done the things…I felt helped."*

Topic	Question: Did you share or discuss any of the information with anybody else? Please explain.
Sharing and support	Participant 3: *"…I go to the support group…" AND "…she's also HIV positive so I used to share the book with her and explain to her what's the book about."* Participant 5: *"I discuss with the other people" AND "…I also make an example about myself."* Participant 15: *"…I explain to them about the things that I read in the book."* Participant 26: *"…I used to discuss with my group mates."* Participant 30: *"There is one person I discuss with…"* Participant 34: *"I discuss a lot…"*

Topic	Question: Is there anything else that you would like to share? Please explain.
Expanding	Participant 3: *"…I wish you can also go the clinics and do the group…because there are people who also want to join the group, those who are also using treatment."*
Gratitude	Participant 5: *"…I can say I thank the group because it brought us important information."*

4.9.2 Participants' responses from the therapeutic relationship intervention group

The TR intervention group had been exposed to a therapeutic relationship over the 24 weeks of the study, but did not participate in the PL programme or receive any information from it. Despite this, the responses in the post-study interviews for the TR intervention group implied that participants had independently identified ways to help manage symptoms. For example, many participants reported that exercise helped alleviate symptoms. Although participants in the TR intervention group were not given exercise as an intervention, it appeared that the exercise performed in the PPTB outcome measure, which was part of the assessment at the data collection points, became identified as an intervention by the participants.

Participants in the TR intervention group, when asked if they had received any information during the study, which helped with symptom management, or if they discussed this with anyone else, brought up comments on the topic of improved wellness, sharing and support and hopefulness and encouragement (Table 4-15). Despite not participating in the PL programme, the participants had learnt some generic knowledge on how to manage symptoms.

No hints of contamination were found during analysis of the interview responses. Similar generic knowledge, with regards to finding support and eating healthily, was known, which appears to be taught during routine care for PLWHA. However, no knowledge particular to the PL programme appears to have been shared with the TR intervention group. One participant in the TR group expressed that within the group people shared their own experiences with fellow participants. Individuals also expressed noticing the positive effects of exercise.

The responses of two participants (participant 13 and 24) indicate that these participants identified the TR intervention group as a group within which to bond with others and attend together. This may have occurred naturally as participants from the TR intervention group shared the same day for follow-up dates with the RA. It is also possible that participants identified those who saw the RA on the same follow-up date as a group because the informed consent form expressed that participants would be put in a group, an intervention group, for the study. However, no effort was made on behalf of the RA to facilitate participants in the TR intervention group to act as a group as this was not the intention of the intervention. The RA met individually with participants for the most part, with the exception of participants who requested to be seen alongside another participant, as explained in Chapter 3.8 (p.98), to complete the interview-administered questionnaires and the PPTB. Despite this, participants appeared to form a group outside of the RA follow-up interview while attending the data collection points, in which they shared information and offered one another support and encouragement.

Table 4-15: Participants' responses from the TR intervention group (n = 13)

Topic	Questions: Did you receive any information during the study about HIV/AIDS that helped you to manage your symptoms? Please explain.
Symptom alleviation	Participant 12: *"…I felt better and alright…"* Participant 23: *"I used to feel weak but now I am strong."* Participant 24: *"…and that helped me…"* Participant 29: *"…I felt better after that."* Participant 31: *"…I feel alright…"* Participant 38: *"…I don't have stress anymore…"* Participant 48: *"…I noticed that my legs were very weak but now they are strong…" AND "…because others were very worse and were very weak but I noticed that they are active now, that group is very helpful."*
Exercise	Participant 12: *"I do the exercises."* Participant 13: *"And I mustn't always sleep all the time I must do something to move my body."* Participant 24: *"… [The group] even taught us how to do exercises…"* Participant 25: *"…give us exercises…"* Participant 29: *"…walking exercises really helped me and the belt we were using to exercise…"* Participant 31: *"…after doing the exercises…"* Participant 38: *"…do my household chores…"*
Sharing and support	Participant 48: *"And being in the group with other people, sharing information you get more experience and I feel happy when I'm in the group with other people because we laugh and chat."*
Hopefulness and encouragement	Participant 13: *"…I was always sad but I felt happy because I was encouraged and they told me that it's not the end of life…" AND "I would love to encourage other people…"* Participant 16: *"…it's not the end of life and you can live for more than 30 years. It doesn't mean you are unique from other people you are not different but you must take care of yourself."* Participant 23: *"…the questions [the RA] asked us like do we regret ourselves, questions like that are the ones that made me feel strong."* Participant 25: *"… [the RA] makes it easy for us to manage everything like telling us that we must not undermine ourselves."* Participant 35: *"… [the RA] tell us that we must not feel different from other people."* Participant 38: *"…I was really encouraged. And I don't have any complaints because everything is going well."*

Topic	Questions: Did you discuss ways to manage symptoms with others? Please explain.
Support and acceptance	Participant 13: *"If next year the group is still continuing I would love to encourage other people, I would tell people that this disease is not different from the other diseases and it's not the end of life."* Participant 48: "*Yes with my [family]. I tell them that this is not the end of life and if they take care of themselves they will not be different from other people; they will live for a long time…"* Participant 29: *"If someone is not alright I discuss with them like my sister–in-law…she used to hide her tablets and…I advised her and now she's alright…"* Participant 35: *"The only person I discuss with is my father. He couldn't accept this disease; he is also HIV positive."* Participant 24: *"We discussed in the group about how to take care of ourselves."* Participant 23: *"Yes, …I discuss with [my friend] because she didn't want to accept she is HIV positive so I advised her and now she's alright."* Participant 38: *"Yes, with my sisters."*

4.10 Summary of results

Forty-nine participants took part in the study, with 26 in the PL intervention group and 23 in the TR intervention group. Attendance of the PL programme and the data collection points was often poor in both groups. There were no statistical differences between groups at Baseline in socio-demographic characteristics, which included age, employment, highest level of education and health literacy. No statistical differences between groups were found at Baseline for clinical characteristics of years since diagnosis, recent CD4 T-cell count, HIV management, medical history of opportunistic infections, co-morbidities or use of analgesics. A statistical difference was only found for the CD4 T-cell count at diagnosis between groups at Baseline.

4.10.1 Changes in pain

The PSS and PIS reduced significantly in the participants in the PL and TR groups over the 24 weeks of the study, indicating an improvement in these outcomes in both groups, both of whom received a therapeutic relationship. The reduction in PSS an PIS in both groups were indicative of clinically meaning changes in pain severity and pain interference[224]. The percentage of participants who had a clinically meaningful improvement in PSS was 67% for both the PL and TR intervention groups at Week 24. Further, there was no significant difference between groups in the number of participants having successful reduction in pain severity ($p = 1$), which is in agreement with the results of the multiple regression analysis for PSS and indicates that a therapeutic relationship appears to be sufficient to bring about these improvements in PSS.

The prevalence of pain in the sample reduced from 100% at Baseline (all participants reported pain) to a pain prevalence of 57% at Week 24. Further, there were no significant differences between groups at any time points in the study. Along with all the other improvements in outcomes for pain, the PMI was significantly improved over time in the 24 weeks of the study with no significant differences between groups.

4.10.2 Changes in secondary outcomes measures

There was a significant decrease in BDI scores over the 24 weeks of study for both groups and no significant differences between groups. This indicated reduced symptoms of depression reported in the BDI, and improvement with regards to this in the participants in the sample.

The results from the EQ-5D VAS and EQ-5D Index, which were used to measure HRQoL, were both significantly higher in the PL intervention group compared to the TR intervention group at Baseline. For the EQ-5D VAS there was a significant effect of time, improving the score over the 24 weeks of the study for both groups. Between intervention groups there was no significant difference for the EQ-5D VAS according to regression analysis and the EQ-5D VAS did not remain significantly higher than the TR intervention group. For the EQ-5D Index an appropriate model could not be found to analyse the data using mixed-model regression. The results of t-tests and a one-way ANOVA indicated that no differences were found between groups at Week 24, despite the difference at Baseline and the EQ-5D Index score improved significantly over the 24 weeks of the study for the study's participants.

Self-efficacy was the only outcome which was significantly higher in the PL intervention group than the TR intervention group over the 24 weeks of the study. The difference in self-efficacy between the intervention groups possibly occurred around Week 8, and therefore there may not be a significant difference between groups for self-efficacy at Week 24. Further, self-efficacy improved significantly in both groups over the 24 weeks of the study and there was no significant effect of the group and time interaction, indicating that by Week 24 both groups had significantly improved in self-efficacy.

There was an effect of time on function in the sample, with significant improvements on the 6MWT, forward reach tests and timed tests over the 24 weeks of the study. No significant differences existed between the groups in these tests at Week 24.

By means of the open-ended questions posed to participants in the PL and TR intervention groups at the end of the study the responses to the study were further understood. Participants from both intervention groups reported benefits in pain and symptom reduction, improved wellness, increased exercise and support. Additionally, participants from the PL intervention group gained knowledge from the PL programme and workbook.

The interventions received by each group were therefore successful in significantly reducing pain severity and pain interference, the primary outcome measures, over time. Further, the secondary outcomes of symptoms of depression, HRQoL, self-efficacy and physical function also significantly improved over the 24 weeks of the study. No differences were found between the groups for outcomes, with the exception of self-efficacy, indicating that the therapeutic relationship alone was effective in bringing about improvement in pain severity and interference, symptoms of depression, HRQoL and physical function.

5 Chapter Five: Discussion

5.1 Introduction

The present study set about to determine the effect of the PL programme combined with a therapeutic relationship, in comparison to a therapeutic relationship alone on pain severity and pain interference amongst rural amaXhosa women LWHA. The effects of both interventions on symptoms of depression, HRQoL, self-efficacy and physical function were evaluated as secondary objectives.

The main results of the study were that the interventions of the PL group and the TR group were both effective in significantly reducing pain severity and pain interference over time and no differences existed between the groups for pain severity or interference.

Initially this discussion will review the attendance, demographic and clinical characteristics of the participants. This will be followed by discussion on the results of the primary outcome of pain, covering pain prevalence, pain severity and pain interference. Thereafter, the secondary outcome measures of symptoms of depression, HRQoL, self-efficacy and physical function will be discussed. The discussion will be completed by exploring the study strengths, limitations, clinical implications and implications for future research.

5.2 Sample and attendance

Low attendance was a consistent feature in both the PL and TR intervention groups in the present study as indicated in Figure 4-2 (Chapter 4.1: p.104). Participation was limited in the six-week PL programme, with the lowest percent of participants attending a session being at Week six of the programme, where only ten participants were able to attend (38%). Low attendance was also common for data collection with data collection being least attended at Week 24 when only 15 participants of the PL group (57%) could attend and 12 participants of the TR group (52%) could attend. The reduced participation possibly limited the effects of the programme and the effect of therapeutic relationship over the 24 weeks of the study respectively. Therefore, sample sizes of studies in rural communities should account for the possibility of poor attendance.

It was expected that the 26 participants in the two PL intervention groups, of optimal size for facilitation[47], would still allow for attrition, based on the results of the study on the effect of the PL programme amongst urban amaXhosa women by Parker and colleagues[46]. However, present study attendance was poorer than the attendance of the PL programme and data collection points in the study by Parker and colleagues[46]. The highest percentage of non-attendance at a PL programme session was 25% in the study by Parker and colleagues[46] and 62% in the present study. For data collection the attendance was also better in the study by Parker and colleagues[46] (92% and 80% for the experimental and control group respectively) compared with the present study (43% and 47% for the PL and TR intervention group respectively).

It was not apparent if non-attendance was due to the study itself or for the reasons given for non-attendance alone. However, the majority of participants who were unable to attend one week were able to attend the following date for data collection in the study. Further, no participants officially withdrew from the study, although the low health literacy of the participants may have made it unlikely for an official withdrawal to occur. Participants expressed that transport, family and community responsibility, working or visiting family in urban environments were barriers for attendance (Chapter 4.1: Figure 4-2; p.104); the same reasons given for other rural amaXhosa LWHA declining participation in the study during recruitment.

The barriers to attendance suggest that change is indicated in this rural area to make health care more accessible[58,59,274]. At times participants expressed not having available finances for transport to the clinic despite having costs paid for by the study at the previous follow-up date or data collection point, indicating the financial burdens of some participants. Further, as using the public transport system is time consuming (inferred by a study in rural KwaZulu-Natal)[275], as is waiting at the clinic for a turn with a HCP, these factors make attending health care more challenging when also taking into account family responsibility, work and finances. For many who live away from the tar road in the surrounding areas of Zithulele, accessing health care in the area is made more challenging by the hilly terrain and dirt roads, which means making further effort, by walking, or expense, by taking a private vehicle[58,59].

Similar barriers appear to extend to the attendance of routine care (C. Young, email communication, November 2016), although attendance of routine care may be better as it was expressed to participants that the study dates should not interfere with or take precedence over their routine care. In light of this, offering health care over and above what is regarded as essential may be burdensome for individuals in this rural context and could be contributed to aspects of the participants' demographics such as unemployment.

5.3 Demographic characteristics

In light of the biopsychosocial nature of pain, differences in pain and its management are expected in individuals[35–39,48,61]. Unemployment, low HLOE and limited health literacy were common demographics in the study participants, which may have contributed to the effect of the study interventions on pain, as these demographics are linked to increased risk of pain and increased severity of pain[7,18,27,74,81,95,96,108,110].

Unsurprisingly, close to 50% of participants were not looking for work, as according to many studies work is one of the most common domains affected by pain in PLWHA[4,17,25]. Apart from pain, participants may have family responsibilities which prevent work, or may perceive their work capacity as reduced as has been found in a large South African study with over 600 PLWHA living in the Eastern Cape[276].

The high unemployment rate in the study sample (82%) was much higher in comparison to the unemployment rate reported in the district within which Zithulele and the surrounds areas are (38%)[45]. However, the higher unemployment rate may be normal for PLWHA with pain in comparison with the general population or PLWHA in the district[7]. Additionally, the participants have a higher HLOE, with more participants having attended high school, than in the population of the district in which Zithulele and the surrounding areas are[45]. The differences in demographic characteristics between the participants and the district suggest that the participants' demographics may affect the generalisability across the district, however the demographics of PLWHA in the district remain unknown.

5.4 State of health assessed by clinical characteristics

The cohort appeared to be relatively healthy according to the clinical characteristics. Despite the relatively healthy state, all participants were experiencing pain at Baseline of the study, with moderate pain intensity and pain interference[87,227]. However, the presence of pain among relatively healthy participants is not unusual as pain is commonly reported amongst PLWHA irrespective of CD4 T-cell count or stage of disease[24].

The study participants had lived with a known HIV diagnosis for a 3.96 years (± 3.25) and had fairly good health, inferred from the mean recent CD4 T-cell count of 461.27cell/µl (± 238.62) of the participants[277] and the majority of participants being on first line HIV management and being largely unaffected by OIs. Participants also appeared to have good disease management, with considerably better CD4 T-cell count in the recent cell count compared to the initial CD4 T-cell count. In addition, as expected for people between 18 to 40 years old, very few comorbidities were reported, bringing about the desired effect in the study design of keeping the effect of co-morbidities on the results to a minimum.

The rural amaXhosa study sample appeared to have better health, with regards to the biomedical factors discussed in this section, in comparison to the urban amaXhosa cohort in Parker and colleagues[7,46]. How the participants' health compared to the health of PLWHA in the areas around Zithulele and the Eastern Cape with regards to HIV management and especially CD4 T-cell count is unknown. In light of this, it should be recalled that the relationship between pain and HIV management or CD4 T-cell count is unclear[8,24,54,73,82,101,112]. There was a much higher percentage of study participants receiving ARVs compared to PLWHA in rural informal localities across South Africa and Black African PLWHA[51]. This was not unexpected as recruitment took place on ARV clinic days but this discrepancy indicates that the results may be more generalisable to PLWHA receiving first line ARVs.

The presence of pain in the relatively healthy study sample, and presence of pain in the urban amaXhosa participants in Parker and colleagues[7,46], appears to be a further testament to the knowledge that pain is complicated in nature, is biopsychosocial, and is contributed to by many biomedical and psychosocial aspects[32,33,35–39,48,60,67].

5.5 Prevalence of pain

A notable reduction, of more than 50%, occurred in the prevalence of pain over the 24 weeks of the study. Despite the possible effect of regression to the mean on the prevalence of pain as a result of 100% prevalence of pain at Baseline[278,279], repeated measures reduce the effect[280]. The consistency of reduction in pain prevalence over the period of study during which the interventions occurred, in both the present rural cohort and urban amaXhosa cohort in Parker and colleagues[46], as well as the improvements seen in the secondary objectives, further validates that the prevalence of pain appears to have reduced in response to the interventions. However, this does not fully eliminate the effect of the regression to the mean, particularly as the prevalence could not increase given a baseline of 100%. As both intervention groups received the TR intervention, the results suggest that a TR intervention is sufficient for reducing the prevalence of pain when compared with a combination of a therapeutic relationship with the PL intervention.

5.6 Sites of pain

The present study found an average of 3 (± 1) sites of pain per participant, which falls above the range of number of pain sites found in the systematic review on pain in PLWHA[24] and is much closer to the number of pain sites experienced by a sample in the USA (2.5)[24,54] than by participants from another rural South African cohort (1)[8,24]. That multiple sites of pain are common is not surprising as there are many sources and influences of pain due to the biopsychosocial influence of pain[60,61]. As discussed in the literature review (Chapter 2.3.3.2; p.23), numerous pain sites could indicate the presence of more than one pathological process occurring simultaneously, or that the person LWHA may be suffering from a central sensitisation disorder[24,117].

The percentages of participants reporting the head and the abdomen as sites of pain in the present study were higher than the rural cohort in the study by Mphahlele and colleagues[8]. Of particular note is the large percentage of participants in the PL intervention group (85%) and TR intervention group (48%) of the present study who reported pain in the head, which differs from another rural cohort of PLWHA in the study by Mphahlele and colleagues[8] (19%).

5.7 Pain severity and pain interference: primary outcome measure

The moderate PSS and PIS[87,227] at Baseline in the present study are consistent with the finding that pain and its management is a problem for PLWHA who experience pain[8,46] and requires better attention and management. As expected, pain severity was more similar to that of other outpatients cohorts than to inpatients cohorts[24].

5.7.1 Changes in pain severity and pain interference over time

The main results in the present study indicate that a therapeutic relationship appears to be sufficient for significantly reducing PSS and PIS over time. A significant reduction in PSS and PIS occurred in the participants over the 24 weeks of the study, with both intervention groups, whilst receiving a therapeutic relationship, achieving the same outcome. Therefore, either intervention, the PL programme and therapeutic relationship combined, or therapeutic relationship alone, appears to be adequate to achieve a reduction in pain severity over time. As the PL programme was not necessary to establish a significant reduction in PSS and PIS, the present study supports the use of the therapeutic relationship for effective pain management in rural amaXhosa LWHA.

The empathetic therapeutic relationship, which developed between the study participants and the RA during data collection in the present study, appears to be sufficient to result in a significant reduction in PSS and PIS over time. The results support the suggestion in the study on urban amaXhosa women LWHA by Parker and colleagues[46] that a care factor may have existed which contributed to the improvements in PSS and PIS observed in both those participating in the PL programme and those who only received the PL workbook.

The results of the present study are supported by many studies which have established that a therapeutic relationship is essential for optimising patient outcomes[156–159,195]. This study supports the notion that the therapeutic relationship has its own effect on outcomes and should therefore be regarded as a treatment itself and that more value and attention should be given to interactions between patient and HCP[156]. The results indicate, as other studies have done so previously[156,197,207,218,219], that the therapeutic relationship has a positive effect on both psychological and physical outcomes, including pain.

In a meta-analysis by Kelley and colleagues[156], the effect size of the therapeutic relationship alone on physical outcomes in people with various conditions, including asthma, fibromyalgia, diabetes and cancer, was small but similar in effect to many other medical treatments. The similarity of the effect of the therapeutic relationship to another intervention (the PL intervention) was seen in the present study too, as both intervention groups had the same outcomes. The trials in the systematic review and meta-analysis analysis by Kelley and colleagues[281] manipulated the therapeutic relationship in various means, including emphasising communication skills and empathy, which were purposeful strategies also used in the present study. The control groups of the studies in the meta-analysis made use of minimising positive effects of the therapeutic relationship and were, therefore, able to determine that an effect size for the therapeutic relationship exists.

A systematic review by Jensen and Kelley[156], on the effect of therapeutic relationships, mentioned that a poor therapeutic relationship could have a negative effect on outcomes in the same way that a good therapeutic relationship has a positive effect on outcomes. Most literature supporting the effect of the therapeutic relationship on outcomes is in the field of psychotherapy[156]. Of interest is that the differences in the therapeutic alliance and empathy in psychotherapy have been found to account for the majority of differences in outcomes, compared with the differences in the other factors which are specific to psychotherapy treatments[282]. This verifies the importance in health care of purposely building good and beneficial therapeutic relationships, as the present study has done.

The role of the therapeutic relationship, which was used as an intervention in the present study, has been validated by numerous research studies, as reported in the review by Jensen and Kelley[156], as an important contributor to the outcomes of psychotherapy. The findings from Jensen and Kelley[156] supported that the therapeutic relationship is predictive of physical and psychological changes, as did the study by Tufekiglou and Muran[194]. The association between a better therapeutic alliance and positive outcomes of psychotherapy was found to be significant and have a medium effect size according to a meta-analysis published in 2011, which supported the findings of three previously published meta-analyses[195,283–285]. It should be noted, as pointed out by Jensen and Kelley[156] that the medium effect size of the therapeutic alliance in psychotherapy is a larger effect than many medical treatments.

Flückiger and colleagues[159] were able to show that the results indicating the medium effect of the therapeutic relationship on outcomes in psychotherapy were robust and reliable by re-analysing the data from a previous meta-analysis and taking into account some variables. The data were moderated for variables such as RCT trials, specific disorders, treatment of specific outcomes related to a specific disorder, CBT treatment and an interest in the therapeutic relationship by the therapist.

One of the challenges with discussing the effects of the therapeutic relationship and comparing it to other research is that to date, no set way of quantifying the therapeutic relationship has been developed[158]. The therapeutic relationship is considered a non-specific element partly characterised by empathy[198,208]. While no measurement of the therapeutic relationship was made in the present study, the empathetic therapeutic relationship was generated in a purposeful manner by the RA as described in the methods (Chapter 3.6.2; p.87).

The natural ability of the RA to show empathy in addition to the training received, appears to have been successful in establishing an empathetic therapeutic relationship between the RA and participants, contributing to a reduction in pain. Communication, both verbal and non-verbal, is a key aspect of the therapeutic relationship in establishing participants' perception of care, which has been indicated in many studies[198,208–210]. In the present study, the RA behaved with valued interpersonal skills such as being friendly, confident, empathetic, encouraging and respectful[198,211].

As discussed, it is primarily the care as well as the trust and attention received as a response to participating in a trial which impacts the outcomes positively[197,221]. Being in a clinical trial also improves researchers' and HCPs' behaviour towards participants, in comparison to routine care given[222]. The impact that care has on an individual is illustrated in the present study, where pain and secondary outcomes were significantly improved as a response to perceiving care[220].

Proposed mechanisms for the effect of care, generated through the therapeutic relationship, on pain include placebo analgesia physiological changes. The release of endogenous opioids and neurophysiological changes have been reported in the presence of an empathetic therapeutic relationship, and reduce pain[156,199–201,286,287]. Three studies in the review by Jensen and Kelley[156] found that the same areas of the brain are activated in two people when there is joint attention and mutual understanding of an individual's state of mind, which enhances the therapeutic relationship by facilitating social cognition[288–290]. Further, the anterior cingulate cortex and the anterior insula both play a role when individuals empathise with a person experiencing pain[286]. In a study by Sarinopoulos and colleagues[287], patients experiencing pain had less pain-related brain activity when a HCP focused an interview on the patient and showed empathy compared to when a HCP focused the interview around diagnosis. Therefore, as the RA in the present study focused on the participant and showed empathy in the interviews. This behaviour may have contributed to the overall effect of the reduction of pain in both groups of participants, who received the therapeutic relationship.

It is important to note that the therapeutic relationship appears to develop over time and with consistency and is not merely about empathetic behaviour but the ongoing nature of it[197,204,221]. The continuous interaction develops trust[204], and together with care facilitates improved outcomes[197,221]. In both the study by Parker and colleagues[46] and the present study, participants were given a consistent message of being cared for by having regular contact and follow-ups with a consistent interviewer. The consistency of person as well as empathetic behaviour the RA portrayed is a contrast to the fragmented care patients commonly experience in the South African public health care system and the impression of the clinic as a hostile environment[291]. The fragmented care, which arises due to high staff turnover and mobile patients[53] combined with the sometimes disrespectful health-professionals, results in dissatisfaction of patients with routine health care[291].

The provision of consistent care through a consistent HCP, which may contribute to the development of an ongoing therapeutic relationship, in which patients are treated well and with care, appears to be an effective pain management strategy for rural amaXhosa women LWHA. In addition to being effective, this approach may well be more sustainable than running an intervention such as the PL programme, which requires peer-leaders and extended patient participation. The appointment of 'named' HCP to allow for the development of therapeutic relationships needs to be prioritised in the platform on which treatment is built for PLWHA experiencing pain. Further, the impression of the clinic as a hostile environment[291] needs to be replaced by an empathetic environment.

5.7.1.1 The influence of self-efficacy on pain

The PL programme, being a self-management intervention, was expected to facilitate changes in self-efficacy, which would result in improvement in outcomes of pain[76,77,142,162]. As discussed in the literature review, previous studies have shown that self-management programmes are effective in significantly reducing pain[76,77,162], and that these changes in pain can be predicted by change in self-efficacy over time[77]. Despite a significant difference between groups during the 24-week study, both groups' self-efficacy improved significantly over time. Although a difference between groups occurred, which was most likely at Week 8, in the study, the outcome suggests that the therapeutic relationship is sufficient to generate change in self-efficacy and pain over time.

5.7.1.2 Clinical significance

The purposeful development of a therapeutic relationship between participants in this study and the RA appears to have been sufficient for bringing about a clinically meaningful reduction in pain severity. Clinically significant reductions in PSS and PIS were found in both intervention groups[224,263]. In the PL and TR intervention group 67% of participants met the clinical meaningful change in PSS[263].

It appears that for rural amaXhosa women LWHA the therapeutic relationship is an essential platform for pain management and alone can bring about a significant improvement in pain severity and interference. Therefore, HCPs who work with rural amaXhosa women LWHA should place more emphasis on developing better therapeutic relationships to facilitate improved pain management for their patients.

5.8 Pain Management Index

On the PMI, inadequate pharmacological management of pain was found at Baseline in all participants. These findings are consistent with the cohort of urban amaXhosa women in a previous study by Parker and colleagues[46]. The results of the present study and those of Parker and colleagues[46] concur with the findings of the systematic review by Parker et al.[24] that indicate that inadequate pain management is common, with 66-100% of participants in the reviewed studies had PMI values below zero[24]. Furthermore, the findings on pain management in the present study are consistent with research on women, and people with low levels of education LWHA, for whom inadequate pain management exists[18,20,26,27].

5.8.1 Change in Pain Management Index over time

The PMI scores in the present study significantly improved in both intervention groups, over the 24 weeks of the study. These results are similar to those from the study by Parker and colleagues[46] over 16 weeks. The PMI measures pain severity against pharmacological pain management[87,88]. In the present study, the PMI improved simultaneously with or following the improvement in PSS. Since change of pharmacological pain management is likely to be negligible in routine care[46,114] and pharmacology is known to have limited effectiveness for reducing pain in PLWHA[22,80], it is likely that the change to PMI occurred as a result of the reduced PSS.

Therefore, the change in PMI in the present study may not be indicative of any change in pharmacological pain management. Rather, participants may have benefited from the therapeutic relationship and improved communication with HCPs to facilitate better pain management. Given the inconsistent availability of pain medication in resource poor settings[53] and the limited efficacy of pharmacological management for pain in PLWHA[22,80], the results of the present study support a shift in focus towards the purposeful development of therapeutic relationships to facilitate reductions in PSS and PIS.

5.9 Self-efficacy: secondary outcome measure

5.9.1 Change in self-efficacy over time

The therapeutic relationship appeared to be sufficient to bring about significant improvements in self-efficacy over time in both intervention groups. There was an effect of group over the 24 weeks of the study where the PL intervention group had significantly better self-efficacy compared to the TR group. However, since no group and time interaction existed and the significant difference between groups seem to be around Week 8, the overall result suggests that the therapeutic relationship is sufficient for improving self-efficacy.

Improvements in self-efficacy are a target outcome of participating in a PL programme[77]. The significant increase in self-efficacy in the PL programme reflects a success of the programme for this variable. These findings are consistent with the study by Lorig and colleagues[77] on people living with osteoarthritis, in which a significant decrease in pain and increase in self-efficacy existed at four months in the experimental group, who participated in a self-management programme for six weeks, compared to the control group[77]. However, in the present study these improvements in self-efficacy were not limited to the participants in the PL group, as participants in the TR group had similar improvements in pain and self-efficacy. It may be that the difference between groups would be more apparent over a longer follow up period[c]. However, at this stage the therapeutic relationship appears to be equally effective in improving self-efficacy in rural amaXhosa women LWHA without the need for participation in the PL programme.

The therapeutic relationship has been shown to improve health behaviours[207], with results similar to CBT[160,165]. Since self-efficacy is integral to positively changing thought patterns and behaviours, which has an impact on health behaviours and outcomes[77,160–163], it is plausible that self-efficacy amongst other health outcomes can be improved as a result of a therapeutic relationship.

[c] The long-term effects of the interventions at one year are being monitored as part of a larger study on pain in PLWHA and will be reported on in publication.

5.10 Symptoms of depression: secondary outcome measure

No significant difference existed between the intervention groups for BDI at Baseline. BDI scores were higher at Baseline amongst rural amaXhosa women in the present cohort compared with the mild to moderate scores in urban amaXhosa women in Parker and colleagues[7,46]. However, despite the positive correlation between pain and depression[16,73,74], the PSS and PIS for the urban cohort was higher than the rural cohort. Taking this interaction into account, the comparison between the cohort of urban amaXhosa women in the study by Parker and colleagues[7,46] further illustrates the effect of the biopsychosocial nature of pain and the complexity of the relationships between pain, depression and other psychosocial elements[292].

5.10.1 Change in symptoms of depression over time

As a significant reduction in the BDI took place over time for the sample, the therapeutic relationship appears to be sufficient in reducing symptoms of depression in rural amaXhosa women LWHA and experiencing pain. Over the 24 weeks of the study, all participants had reductions in depression from moderate depression to minimal depression on the BDI[237]. The PL programme did not significantly increase the improvement in BDI above that of the therapeutic relationship alone, despite previous research indicating the worth of self-management programme participation in reducing depression[76,77,162]. The present study is consistent with previous authors who have reported and demonstrated the beneficial effects of the therapeutic relationship on psychological symptoms, including depression[156,158,293].

With observations of the graphs for PSS (Chapter 4.4.3: Figure 4-7; p.118), PIS (Chapter 4.4.4: Figure 4-8; p.123) and BDI (Chapter 4.5: Figure 4-10; p.128), the BDI scores had a more gradual descent than the PSS and PIS in the present study. Similar to the results from the urban cohort treated with the PL programme, it is likely that the reduction in pain in the present study occurred before improvements in depression. Thereafter, it is probable that these two symptoms were inter-related and affected each other[74] as expected in a biopsychosocial framework of pain[35–39]. This is likely to be the case with HRQoL, which also effects pain[16] and therefore influences the biopsychosocial framework of pain[60].

5.11 Health-related quality of life: secondary outcome measure

5.11.1 Health-related quality of life at Baseline

Consistent with other South African cohorts the present study found that rural amaXhosa women LHWA have a reduced HRQoL compared to their urban counterparts[7,17,46,72,98]. The baseline EQ-5D VAS of the rural cohort was lower (59.9% ± 16.6) than the baseline EQ-5D VAS of two urban cohorts of PLWHA (66.67% & 62%)[7,46,106].

HRQoL was the only outcome which was significantly different at Baseline in the present study. The PL intervention group had a significantly higher EQ-5D VAS and EQ-5D Index than the TR intervention group. Participants from the PL intervention group all attended Pumalanga clinic, while the participants from the TR intervention group attended Ngcwanguba CHC. The differences in the two communities in which participants lived, which are two distinct areas, each with its own clinic, road networks and tribal authority may have affected the perception of HRQoL despite there being no significant difference in age, employment and education[58–62]. Interestingly, there was no difference between groups in pain at Baseline. Previous studies have emphasised the links between pain and HRQoL[41,72], however this link at Baseline was not apparent in the present study's participants. This suggests that there are complex mechanisms at work in the interactions between pain and HRQoL, which would be expected considering the biopsychosocial framework of pain[35–39].

5.11.2 Change in health-related quality of life over time

The significant improvements in EQ-5D VAS in all participants (who were all receiving a therapeutic relationship), over the 24 weeks of study, differed to the study with their urban counterparts by Parker and colleagues[7,46], which found no significant difference over time from Week 0 to Week 16. The shorter time period of the study in Parker and colleagues[7,46], may have limited the effect of time on HRQoL. However, this difference could also occur as a result of the psychosocial differences in communities[58–62] or more intentional emphasis being placed on the development of an empathetic therapeutic relationship in the present study. The improvement in HRQoL in the present study may additionally suggest that a greater potential for improvement in the EQ-5D VAS in rural amaXhosa PLWHA exists compared with urban amaXhosa PLWHA[7,46].

The present study found no significant difference for the EQ-5D VAS and EQ-5D Index between groups at 24 weeks of the study, as is the case with most other outcomes, and the participants of the study significantly improved in both these measurements. This indicates that the therapeutic relationship appears to be sufficient to improve EQ-5D VAS and EQ-5D Index amongst this rural amaXhosa sample of women LWHA.

5.12 Function: secondary outcome measure

In comparison to a healthy cohort, the functional performance amongst rural amaXhosa women LWHA was reduced at Baseline, similarly to other cohorts of PLWHA[78,79,294].

There was a positive effect of the study interventions on function. In the present study both intervention groups improved significantly over the 24 weeks of the study for the 6MWT, forward reach tests, timed repeated sit-to-stand test, timed repeated reach-up test and timed belt-tie test. Despite only the participants of the PL programme having formal exercise sessions and being encouraged to increase their active exercise behaviour[47], the only significant differences between groups was for the timed, repeated reach-up at Weeks 8 (the PL intervention group was significantly quicker) but by Week 24 no significant difference between the groups existed. Another study, which compared an experimental group, participating in a similar self-management intervention for people with osteoarthritis awaiting arthroplasty, to a control group, who received routine care, found no significant differences in function between groups either[192]. In the present study both interventions, the PL programme and the therapeutic relationship combined or the therapeutic relationship alone appear to have the same limited effect on function.

The limited effect on function may partly be a result of the type of tests performed in the PPTB. The PPTB was chosen as it was a valid and reliable objective measurement of function, which had previously been used with people in pain and PLWHA living in the USA[78,253]. In light of the biopsychosocial nature of pain, future studies amongst rural amaXhosa women might consider modifying the PPTB to assess function by including functional tasks with more relevance to women living in rural areas. This would give more meaning to the functional tasks[60]. For example, walking tests could be modified by incorporating carrying wood or water on one's head during the test[43].

As physical tests in the PPTB can be evaluated as individual tests[254], each test will be discussed in more detail in the following section.

5.12.1 Physical performance task battery – change in 6MWT over time

The baseline 6MWD for the sample (357.19 metres ± 74.79) was, as expected, under the normative values for functional performance from a healthy cohort, despite having a lower sample mean age[294]. In both intervention groups pain and the 6MWD improved together, which is consistent with the biopsychosocial nature of pain within which the inter-relationship between pain and functional performance can be better understood[48,61,78,79]. However, as no evidence was found on the clinically important difference in distance for the 6MWD relevant for PLWHA, the change in 6MWD, although significantly better, is difficult to interpret.

5.12.2 Physical performance task battery – change in forward reach tests over time

As with the 6MWT, participants in both the PL and TR intervention groups significantly improved in the forward reach tests over time, indicating that there was an improvement in balance and strength in the sample[254,295]. Improvement occurred in both groups despite only the participants in the PL intervention group taking part in structured exercise sessions, which may have improved their balance and strength[47].

Although improved balance may have been a benefit of the therapeutic relationship, it is more plausible that a learning effect may have occurred. The gradual consistent improvement in the performance of this test in comparison to the faster initial improvement in the 6MWD implies that a learning effect existed. Repeating the test twice in one session did not alter the intraclass correlation coefficient (ICC) during testing of the validity of the forward reach tests in people with lower back pain[253] and in the original development of the tool (ICC = 0.81[295]). However, in studies of people with Parkinson disease the test re-test ICC was not consistent[296]. No studies reporting on a learning effect in the forward reach test could be found. In addition, no literature reporting on the clinically important difference in distance reached on the forward reach in PLWHA could be found, limiting interpretation of the difference recorded.

Although a learning effect may have existed, there is also a contextual possibility that may have contributed to the improvement in forward reach. Rural amaXhosa women need particularly good dynamic balance to allow them to carry wood and water on their heads as they walk. All participants had moderate pain interference with function at Baseline but over the course of the study pain improved in both intervention groups. It is possible that as pain improved, participants started to participate in the activities of carrying wood and water. These activities may then have resulted in improvements in balance. Carrying water is the woman's role in traditional family life and vital for survival, as water is a basic necesssity[43]. Therefore, it is likely to be one of the first things women would return to doing as soon as they increased in physical performance.

5.12.3 Physical performance task battery – change in timed, repeated sit-to-stand, timed, repeated reach-up and timed belt-tie tests over time

Each timed test improved significantly in both groups, although the reality of the improvement is marginal due to the brevity of the tests. The marginal improvement found in the present study suggests that the appropriateness of these tests may be limited in an outpatient study cohort who are ambulant and independent in many tasks. Further, a learning effect may have come into play as with the forward reach tests.

Previous research suggests that a learning effect occurs with repeated measures over time for the timed, repeated sit-to-stand test[297]. No evidence regarding the effect of repeated measures over time on the timed, repeated reach-up and the timed belt-tie test could be found. However, it is possible that a learning effect occurred with these timed tests too. Further, the belt-tie test was the least stable of the functional tasks in a study on the development of the PPTB in terms of reliability, which is most likely due to the task's complexity[252]. This also suggests that it is possible that repeated measures may lend themselves to mastery of the tasks and improve over time due to a learning effect[298].

5.13 Post-study structured interviews

The responses to the post-study structured interviews offer similar stories to the quantitative results of the study, further validating the effect of the therapeutic relationship on pain, depression, HRQoL, self-efficacy and physical function. Pain or symptom alleviation, improved function, reduced symptoms of depression and supportive community each emerged as benefits to participants from both groups.

The one topic not shared between groups related to pain alleviation. Despite the improvements in PSS and PIS in both groups, the topic of pain alleviation was only made explicit by participants from the PL group. Comments in the TR group indicated symptom relief by stating that they felt “alright” or “better”, which may refer to either pain alleviation or other symptoms.

The topic of pain, or in the case of the TR intervention group, symptom alleviation, frequently arose in conjunction with exercise and being active. This was surprising as only the PL intervention group were explicitly given knowledge regarding exercise, partook in exercise classes and were encouraged to do exercise through goal setting and action planning. Nevertheless, the TR intervention group, who were not educated about exercise, used exercise as a tool to improve symptoms. It may be argued that the TR group were exposed to exercise by performing the PPTB at each follow-up. Participants may have come to regard these exercises as treatment. One participant said “…give us exercises…” possibly referring to the RA, although it is unclear. This may have helped improve the function of the TR intervention group[146,148,149].

Consistent with the reduction in BDI scores, participants in both groups made comments which implied that reduction in symptoms of depression and anxiety was as a result of support. The support mentioned by the participants in the TR group mostly appeared to be in relation to other family and community. However, one participant mentioned being asked questions about whether she "regrets" herself, which resembles questions asked in the BDI. These questions if asked by an interviewer in a caring nature have the potential to increase the patients' trust and effect of the therapeutic relationship[237,299]. The topic of support, contributed to the finding that the therapeutic relationship influences psychological and physical health outcomes[156–159,197,207,218–220] and may be sufficient to significantly decrease pain severity and the impact of pain on function.

Further, two participants in the TR group made comments which appear to imply that they perceived the follow-up data collection sessions as a group. This perception could be contributed to by several factors including participants in an intervention group sharing the same interviewer, appointment day and all being women, LWHA and of similar age. At times, participants in the study, in both intervention groups, requested to do the questionnaires simultaneously with one or two others. The RA obliged them, as discussed in Chapter 3.8 (p.98), if adequate consent from each participant was given and no hesitancy was observed. Participants were happy to share their experiences and were not reluctant to do so in front of others. Being able to initiate this as a setting in which to share in a group, may have contributed to improved health outcomes in the TR group. This suggests that rural amaXhosa women in this cohort are able to create self-initiated groups and find support this way, which is a shared ability with their urban counterparts who also set up their owns groups[46].

Interestingly, participants in both groups gave the impression of having gained some knowledge of how to manage some symptoms. The sources of information on how to manage symptoms appeared to differ. In the PL group, the source of information was primarily through facilitation and the PL workbook, whereas in the TR group, information appeared to be shared amongst fellow participants and were suggestive of being learnt from routine care.

Although there was no apparent inter-group contamination, there may have been an element of intra-group contamination. Research indicates that pain can be modulated by expectations, which can cause a placebo or nocebo effect[300]. As participants in the TR group expressed that exercise appeared helpful for symptom management, and one participant expressed that participants in the TR group shared information with fellow participants, results of the TR intervention group may have been affected if participants shared this learnt information that exercise was helpful for managing symptoms[300].

Participants of the PL programme expressed the usefulness of the group and benefit from the exercises which they participated in. Additionally, a suggestion was made by one participant to run more groups at clinics for people who wished to join. Participants from both groups appeared to accept exercise as beneficial and were open to being part of groups. The responses from the interviews in both groups were suggestive that interventions of this type are acceptable to rural amaXhosa women LWHA.

5.14 Effectiveness of the interventions

The therapeutic relationship intervention was feasible in this cohort and the significant improvements in pain, depression, HRQoL, self-efficacy and function in both groups are indicators of its effect. Despite low attendance at data collection dates, significant differences in the primary and secondary outcomes occurred.

Although the efficacy of the PL programme independent from the therapeutic relationship is difficult to ascertain, it does not appear more effective than the therapeutic relationship alone as an independent intervention. It appears that the PL programme is accepted amongst rural and urban amaXhosa LWHA. It's feasibility, however, is questionable. The poor attendance of the PL programme, particularly in one of the two PL groups (which was consistently very poor), suggests that the PL programme may not be feasible for many rural amaXhosa women in this area.

The efficacy of the PL programme may differ if it were therapist-led. Both the study sample and the urban amaXhosa cohort in Parker and colleagues[46] had a lower HLOE compared with two studies in the USA, which endorsed peer-led self-management programmes, both of which had a mean HLOE of over 13 years in school[76,162]. A South African study of participants who had mostly attended high school (eight to 12 years of education) indicated that a therapist-led self-management programme, with education and exercise, was more effective than usual care for people living with osteoarthritis[192]. However, the self-management programme for people with OA was not compared with peer-led self-management in this cohort and the impact of HLOE, in South African contexts, has not been established for self-management programmes.

Furthermore, regarding the HLOE of the cohort, the PL workbook was pitched for people with at least seven years of education[7]. For the urban amaXhosa cohort for whom it was developed, this was appropriate. However, in the present study a large percentage of the PL intervention group stopped attending school before completing seven years of education. The efficacy of the PL programme may therefore partly be affected by the PL workbook being tailored for a higher HLOE than that of a large percentage of the rural amaXhosa cohort. A modified version of the workbook may need to be developed if the self-management intervention is to be enhanced. In addition, developers of modified editions of the PL workbook may need to consider that the Flesch-reading scores may not be suitable for use in rural South Africa, when comparing reading skills with international standards[301].

5.15 Strengths and limitations

The CONSORT guidelines, drawn up to facilitate quality of randomised controlled trials, were used to evaluate the strengths and limitations of the present study (Appendix K; p.374)[302].

5.15.1 Strengths

The main findings of this study were unexpected. Finding something unexpected reduces the likelihood of bias and also provides a platform for a new perspective and for best-practice to be better informed by current research and not on assumptions or hypotheses[298].

The therapeutic relationship intervention has been thoroughly described in the methods (Chapter 3.6.2; p.87) with regards to how the RA was chosen, which qualities the assistant needed to possess, the training the RA received and the procedure of the intervention itself. Showing empathy was vital to the intervention and therefore how it was fostered in the RA has been explained in detail. Future research using a therapeutic relationship intervention could therefore be modelled on this method. Further, comparisons between results of the present study and other studies, using a therapeutic relationship, can take into account the method in which the therapeutic relationship was developed.

Using clinics as the setting for the implementation of the study interventions meant that the research could study the efficacy of the interventions in a realistic setting, as clinics are the most accessible place of health care and the primary source of HIV care in the areas around Zithulele[53]. Evaluating the interventions by intention to treat strengthens the study's ability to be realistic, by allowing for usual occurrences and challenges, such as the low attendance, to contribute to outcomes. The main finding of the study, which found the therapeutic relationship in this rural setting amongst amaXhosa women LWHA to be effective in significantly improving pain, independent of the PL programme, is therefore a realistic outcome in clinical health care.

The shared isiXhosa language between participants and the RA or peer-leader reduced misinterpretations and increased the participants' feeling of being understood by the RA[303]. This would have been important for establishing a better therapeutic relationship, especially as the presence of an interpreter creates an intermediary, whom the attention is diverted towards, reducing the direct interaction of a therapeutic relationship[304].

This study contributed to research which aids better pain management for PLWHA, which is valuable as pain is generally poorly managed in PLWHA internationally[24]. Further, as HIV/AIDS has become known as a chronic debilitating disease[9], and pharmacological interventions available in South Africa have limited efficacy[22,80], it is imperative that more research is done to determine effective non-pharmacological interventions for pain in PLWHA, which the present study was able to contribute to. In particular, it adds to the few studies on pain management in PLWHA in rural South Africa[6,8,34,41,114,276], which is of importance, as between 10.4%-13.4% of the rural population in South Africa are PLWHA[51]. Furthermore, it was the first study to address pain amongst rural amaXhosa women LWHA. In doing so, this study establishes more literature specific to vulnerable groups, such as women and people in poverty, who commonly receive poor pain management[18,20,26–28].

Further, the findings of the study frequently complemented other research. The pain characteristics found in the present study were in line with those in the systematic review in the paper by Parker and colleagues[24], highlighting that pain is a problem for rural amaXhosa women LWHA as well. Secondly, the finding that the therapeutic relationship was sufficient as an intervention, independent from the PL programme, to significantly reduce pain in rural amaXhosa women LWHA, complements many papers indicating the positive effect of the therapeutic relationship on physical and psychological outcomes, including pain[156,197,207,218,219]. It also offers a plausible idea, although not a definite one, that the therapeutic relationship may be partly responsible for the reason the workbook in the previous study amongst urban amaXhosa women LWHA was as effective in significantly reducing pain as the PL programme coupled with the workbook[46].

5.15.2 Limitations

The following limitations should be taken into account with interpretations of the results and main findings of the study.

Low attendance was a major limitation of the study, which may have limited the effect of the PL programme by restricting the development of self-efficacy[164]. Additionally, the low attendance at data collection dates may have restricted the development of the therapeutic relationship despite efforts being made to aid attendance.

Consistent effort was made to aid attendance, through appointment cards, coinciding study dates with follow-up dates for routine care, regular cellular phone call reminders of follow-up appointments and giving participants the monetary value of transport before the follow-up date. However, contacting participants was difficult at times due to the lack of electricity for charging phone batteries[45] and poor cellular phone signal. As there were few participants in formal employment, and grants are the main income for many households in the Eastern Cape, it is likely that poverty may have contributed to the low attendance (Chapter 4.1: Figure 4-2; p.106)[6]. Further, there were reasons for non-attendance, which had to do with family responsibility and work.

If it were feasible for participants to attend the clinic for the data collection on any day of the week the attendance may have been better. However, there are few rooms at the clinics and a room was not available daily. Therefore, if participants were unable to attend data collection on the first day, a second day in the following week was given as an option. Despite attempts to improve attendance at data collection in this way, attendance remained limited.

Secondly, transport problems, one of the common reasons for non-attendance in the study, are difficult to reduce. Despite providing money for transport, transport remained a problem, and participants may have used the money on other pressing needs before the next follow-up. If participants transport was organised by the study it may create suspicion in the community as to why individuals were given this attention. Home visits create the same problem of suspicion and have the potential to reduce privacy if other family members are present. The bigger problem with home visits is that it changes the intervention, changing it from an intervention that can be implemented in a clinic into an intervention which requires more resources.

The limitation of low attendance should be highlighted as it indicates that there are many barriers to receiving health care in this rural area in South Africa. As far as the author is aware, no research exists for comparing non-attendance of scheduled clinic appointments in rural versus urban areas in South Africa. Participants from the present study appear to have had more barriers for attending the clinic than the urban cohort[46]. In the research setting, there is limited access to clinics due to distances between clinics, few public transport routes and high costs of public transport, which might have contributed to the low attendance of follow-ups in the present study[45,58,59,275]. Additionally, the higher employment rate and participants receiving disability grants in the study by Parker and colleagues[7,46], compared with the demographics of the participants in the present study, may have financially aided better attendance amongst the urban cohort than the present study's rural cohort.

The most significant limitation of this study is the large amount of missing data. Despite having a limited data set, appropriate statistical models were found for analysis. To reduce the bias in the interpretation of results, instead of using an ANOVA, which may have distorted the results, model regression analysis was performed. Further, conservative findings were maintained in the regression analysis, where the best model or, failing to find a best model, the most conservative one was chosen from models with significance. Corrections for error in significance were also conducted. If appropriate, no modelling was done and other statistical methods were used.

There was reduced power at Week 24 to detect a difference between groups due to very low attendance, 12 participants, in Week 24 in the TR intervention group (Chapter 4.1: Figure 4-2; p.106). To attain adequate power, 13 participants in each intervention group was necessary, as calculated prior to recruitment (Chapter 3.2; p.77). The large amount of attrition was unexpected, considering the attrition rate in the study by Parker and colleagues[46] amongst urban amaXhosa women LWHA. Due to the reduced power at Week 24, a reduced probability exists for the significant effects of time on pain and many secondary outcomes over the 24 weeks of the study in the TR group. There is also less probability that no significant differences existed between the efficacy of the PL group and the TR group.

Another limitation which arises from the low attendance is that it is unknown whether, apart from the reasons given for non-attendance, the participants who did not return were doing well and improving in the outcomes or the opposite. Therefore, the study results which indicate improvement in outcomes might be biased due to the amount of non-attendance. Fourteen participants of the sample (29%) were unable to attend Week 12 and Week 24, of whom nine participants additionally were unable to attend Week 8.

The participants were all amaXhosa women living in the areas around Zithulele, a rural area in the Eastern Cape, and managed by the Zithulele ARV programme. The study results showing a main effect of time on reducing pain in the presence of a therapeutic relationship, are not generalisable to all rural amaXhosa women LWHA but to women of similar living conditions to the areas around Zithulele and similar health. The study results may also not be applicable to amaXhosa men, urban amaXhosa women or to other cultural groups. Further studies, using randomisation, are indicated across more districts, for example in the Eastern Cape, and between gender, to understand the effect of the therapeutic relationship in rural amaXhosa women and men.

As a sample of convenience was used, the generalisability of results may be reduced. The study used two clinics, which were in the Zithulele ARV programme and identified as suitable, and all participants at one clinic were stratified into an intervention group. Although this study design decreased the chance of contamination, the sample populations in these two clinic areas may not be homogenous, as demonstrated by different EQ-5D VAS and Index scores. Therefore, the generalisability of results across participants in these two intervention groups may be reduced.

With further regard for the study design, maintaining the RA as a single-blind in this setting was challenging especially since the study avoided participants having two hospital visits in a week for the study. For Week 4, the data collection date and the Week four PL group session at Pumalanga clinic was set up on the same date. It was important, due to limited space and a small clinic area that the participants were not seen attending the PL programme. Participants were asked to be discrete in arriving at the group session and, as it was in another section of the clinic, participants were able to maintain this. The communities in the areas around Zithulele have close relationships due to the structure and nature of the community, which shares tribal authority, has traditional ties to the land and years of history with neighbouring families. It was also possible that the RA could hear reports of participants taking part in the PL programme from the community if this information was not managed well. Participants were explicitly told to keep the intervention group they participated in unknown to the RA, however it was unclear whether blinding was maintained throughout the study. The RA was asked to report if the intervention group of any participant was revealed to her or was suspected by her. No reports of this kind were made but the potential for contamination cannot be ruled out.

Other objective tests for function may be more applicable in future studies on ambulant PLWHA. The results of change over time for the forward reach tests and the timed tests of sit-to-stand, reach-up and belt-tie in the PPTB may have been subject to a learning effect over time[297] or appear to be negligent or of unknown clinical meaningfulness in function. For assessing function objectively, accelerometry appears to be a good alternative to the PPTB as it is measures ongoing physical measure of general function, including sedentary behaviour and physical activity[251].

Finally, the results of the present study indicate the effects of the PL programme and the TR over 24 weeks of study. Although this is a longer time period compared to the study by Parker and colleagues[46] on the effects of the PL intervention on women LWHA, 24 weeks is not long enough to show long term effects of the interventions[141,165]. Long-term effects are being monitored at one year, as mentioned earlier, to determine the effect of the PL programme and the therapeutic relationship over longer periods.

5.16 Clinical implications

The results of this study suggest that a purposively developed empathetic therapeutic relationship is sufficient to significantly reduce PSS and PIS over time. The results do not appear to justify the implementation of the PL programme for rural amaXhosa women LWHA. Asking participants to attend more appointments at the clinics than necessary for quality care is unethical due to the financial burden created by transport, and possible absenteeism from work. Additionally, it adds burden to the health care system unnecessarily. In response to this research, the health care system should address barriers to the development of better therapeutic relationships and implement systems that facilitate therapeutic relationships. These systems would include addressing staffing levels, training in empathetic communication and increasing consultation times.

As mentioned previously, patients experience a mix of committed, empathetic staff and disrespectful staff in the South African health care system[291,305] and in rural areas a high-turnover of staff is common[53]. Appointing a sufficient number of staff who are dedicated long-term HCPs to ARV clinics, incentivising long-term commitment in a clinic for HCPs and implementing training in empathetic communication may improve the development of therapeutic relationships over follow-ups[212–214].

It appears to be important that the therapeutic relationship was developed with the same consistent RA, acting in the place of a HCP. Allocating PLWHA to consistent 'named' HCPs, who remain committed over time may be necessary to help to reduce pain in PLWHA.

Although the RA in the present study showed a natural ability to develop and improve a therapeutic relationship with others, research shows that formal training in communication improves the therapeutic relationship[157,212–214]. Heath care professionals and other workers involved in patient care should be trained to foster a beneficial therapeutic relationship and learn about the impact of the therapeutic relationship on health outcomes. The perspective of the therapeutic relationship as an intervention, which can be beneficial or harmful, and therefore has ethical implications, needs to be adopted among HCPs as a platform for further intervention to take place[156,194]. Further, fostering the therapeutic relationship ties in with the patient-centred approach and biopsychosocial approach endorsed by HCPs[157].

The follow-up interview took 30 to 45 minutes to complete, and may mean that participants may need regular visits with dedicated time to develop a therapeutic relationship. As time is a scarce resource, due to low staff numbers in the health care system it may continue to be a barrier for improving the therapeutic relationship[53]. A TR intervention programme, which is similar to that used in the present study in involving interviewing PLWHA on health outcomes including pain, depression and HRQoL by a trained and purposively empathetic non-HCP, could be adopted, if time is found to be a factor for HCPs and funds exist for training non-HCPs.

Further research is indicated in order to better understand the therapeutic relationship and self-management programmes, in order to enhance its use in practice with PLWHA.

5.17 Research implications

Being limited to 24 weeks of study, a study which continues with follow-up until one year is necessary to determine long-term effects of the therapeutic relationship in comparison with the PL programme combined with the therapeutic relationship. As mentioned previously, ethical approval has been obtained to continue to follow the participants to one year to further evaluate the effects of the intervention. These results will be reported on in publication.

In the present study, no structured measurement of the therapeutic relationship was made. Although difficulties arise in quantifying the therapeutic relationship, in future research it would be worthwhile to quantify aspects of it, in order to study whether there is a correlation between the degree of trust or empathy and the change in outcomes. Measures such as the consultation and relational empathy (CARE) measure[306], the Wake Forest physician trust scale (which measures patient's trust in HCPs)[307] and a valid and reliable measure of the trust HCPs have in their patients[308] could all be used to measure empathy and trust in the physician-patient therapeutic relationship. Additionally, as the experience of HCPs by patients is mixed[291,305], understanding any negative effects of poor therapeutic relationships is valuable.

Having regular consultations with a consistent HCP appears to be necessary to build a sufficiently effective therapeutic relationship for alleviating pain, as found in the present study. Future research could compare the efficacy of having regular consultations with a consistent HCP in comparison to the usual setting where patients frequently see different HCPs on pain and other health outcomes in PLWHA. This would determine whether long consultations, as were used for interviews in the present study, was necessary for significant pain improvement or whether regular meetings with a 'named' HCP is sufficient for the significant change in pain.

Although there were no significant differences between the intervention groups, except for self-efficacy, the efficacy of these interventions has only been studied broadly in PLWHA between 18 and 40 years old. Further research into whether there are subgroups for whom participation in the PL programme yields significantly different results to the TR intervention should be done. The PL programme, which is based on the self-efficacy theory[160], has many similarities to self-management programmes, in which developing self-efficacy is integral to improving health outcomes[77,160–163]. Research suggests that people with pain and low self-efficacy are of particular interest when identifying subgroups for whom the PL programme may benefit the most. If the PL programme is significantly more beneficial for a subgroup of PLWHA, guidelines for indication of participating in the PL programme could be developed.

Further, clarifying the most effective way of facilitating the programme, whether peer-led or therapist-led, in cohorts in South Africa may be valuable for future comparisons of the PL programme to other interventions, such as the therapeutic relationship. Previous research, in the USA, indicated that neither HCP-led or peer-led self-management programmes were superior for PLWHA[76,162]. However, the contextual differences, including education as discussed earlier in this chapter (Chapter 5.14; p.182), between South Africa and the USA may influence the effect of a peer-led self-management programme. A South African study assessing a self-management programme for people with osteoarthritis similar to that of the present study showed that participation in a physiotherapist-led programme significantly improved pain compared to participants in the control group[192]. In contrast, the significant improvements in pain in South African participants who participated in the peer-led PL self-management programme in Parker and colleagues[46] and the present study appear not to be better than the therapeutic relationship alone or workbook alone. If comparison between peer-led or therapist-led programmes are studied, the running of future PL programmes should take the poor attendance into account during planning its design.

As a dearth of research is performed in rural areas, limiting comparisons between urban and rural areas, future studies should be considered in rural areas as well as urban areas. For further research in rural areas, it is recommended that possible poor attendance is well accounted for in the sample size calculation.

6 Chapter Six: Conclusion

Pain is one of the most common symptoms of PLWHA[2–5]. The high prevalence of pain in South Africa amongst urban amaXhosa women LWHA, is likely to also exist in rural amaXhosa women LWHA[7,8]. As pain is a biopsychosocial construct[35–39,60,61], culturally appropriate and effective interventions which manage pain are needed[6,8,32–39]. Further, the need for better pain management has increased as HIV/AIDS has become recognised as a chronic debilitating disease[9] and as the prevalence of HIV in South Africa continues to rise, resulting from successful ART rollout[30].

The PL programme, which was identified as an effective non-pharmacological intervention for managing pain in urban amaXhosa women LWHA[46], was tested amongst rural amaXhosa women LWHA to determine its effectiveness amongst their rural counterparts. This was done in light of the biopsychosocial differences between rural and urban amaXhosa people[40–45,49,51,52]. Further, as initial research on urban amaXhosa women LWHA who participated in the PL programme suggested that an empathetic therapeutic relationship may have added to the improvement in pain, the extent of the effect of the therapeutic relationship on pain in rural amaXhosa women LWHA needed to be determined[46].

This study aimed to determine the efficacy of the PL programme combined with a therapeutic relationship in comparison to the therapeutic relationship alone in rural amaXhosa women LWHA. There were no significant differences between groups for the primary outcomes, pain severity and pain interference. Most other health outcomes, specifically symptoms of depression, HRQoL and function were not significantly different between groups, although a significant difference was found between groups for self-efficacy. Significant improvements in pain severity and pain interference were found over time for both groups. Additionally, significant improvements were found for symptoms of depression, HRQoL, self-efficacy and for most functional tasks of the PPTB. Therefore, the therapeutic relationship, and the PL programme combined with the therapeutic relationship, are both beneficial for managing pain in rural amaXhosa women LWHA. As significant improvements occurred in both groups, it appears that the therapeutic relationship is sufficient to manage pain in rural amaXhosa women LWHA. A study which continues to follow the participants to one year is needed to further evaluate the effects of the interventions in the long term, which the larger study will address as mentioned previously and will report on in publication.

Currently, the results do not justify the implementation of the PL programme for managing pain in rural amaXhosa women LWHA. However, further research to determine whether the PL programme is more effective for subgroups, such as PLWHA with low self-efficacy is indicated.

Finally, the therapeutic relationship needs to be recognised as an intervention by HCPs. A therapeutic relationship should act as a platform for further health care in order to provide effective and adequate pain management amongst rural amaXhosa women LWHA. The development of empathetic therapeutic relationships in health care for rural amaXhosa women LWHA needs to be prioritised. Further, emphasis on training HCPs to establish and improve empathetic therapeutic relationships with rural amaXhosa women LWHA is indicated for this population. In addition, health care systems which facilitate a more empathetic environment, where patients can have regular consultations with a consistent 'named' HCP should be established.

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8 Appendices

Appendix A: Demographic questionnaire

Allocated no: _____
Date of birth: _____ (day/month/year)
Village and directions:
_____
_____
Closest clinic: _____
Contact numbers: 1. Mark with a * if this is a personal number
2.
3.
HIV status (tick):

□ Stage 1 □ Stage 2

□ Stage 3 □ Stage 4

Date of diagnosis: _____ (day/month/year)
CD4 at diagnosis: _____
Most recent CD4+:_____ Include date:_____
(day/month/year)

HIV management:

□ Monitoring

□ First-line ARVs Date initiated _____
(day/month/year)

□ Second-line ARVs Date initiated _____
(day/month/year)

Opportunistic Infections:

□ Tb - Pulmonary □ Tb - Extra-Pulmonary

□ Oral Candidiasis □ Syphilis

□ PCP □ Human Papillomavirus/Genital Warts

□ Toxoplasmosis □ Molluscum Contagiosum

□ Cryptococcal Meningitis □ Seborrhea

□ Genital herpes □ Folliculitis

□ Vaginal Candidiasis (thrush) □ Pelvic Inflammatory Disease

Co- Morbid Diseases (eg. Diabetes Mellitus, Hypertension):

_____
_____
_____

Type and number of analgesic medications:

□ Paracetamol □ NSAID's

□ Mild opioids □ Strong opioids

□ Adjunctives □ Other: _____

How long have you been taking the above mentioned medications?

_____
_____
_____

Highest level of education reached: _____(grade at school)

_____(higher level of education-define)

Occupation:

□ Student □ Employed

□ Temporary employment □ Unemployed- looking for work

□ Unemployed- not looking for work

□ Unable to work- Disability Grant

Other (please specify):

_____

Appendix B: The "SOS" health literacy screening tool Instrument

The "SOS" health literacy screening tool	**Allocated no: _____**

1. What is your highest level of education?

□ School Indicate highest grade achieved: _____

□ Higher level of education Indicate highest level achieved: _____

2. How would you rate your ability to read?

□ Excellent or Very Good (Kakuhle kakhulu)

□ Good (Kakuhle)

□ Okay (Ndiyakwazi njee)

□ Poor (Kakubi)

□ Terrible or Very Poor (Kakubi kakhulu)

3. How often do you need to have somebody help you read instructions, pamphlets or other written material given to you by your doctor or pharmacy?

□ Never (Andidingi ncedo)

□ Rarely (Manqaphanqapha)

□ Sometimes (Ngamanye amaxesha)

□ Often (Ixesha elininzi)

□ Always (Lonke ixesha)

Appendix C: Outcome measures

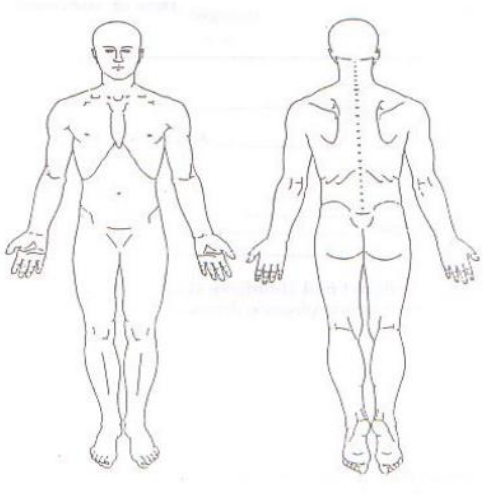
Appendix C/1: Brief Pain Inventory English and Xhosa versions

Brief Pain Inventory - English	**Allocated no: _____** **Date: _____**

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain during the last week?

Yes No

2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



3. Please rate your pain by circling the one number that best describes your pain at its ***worst*** in the last week.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

4. Please rate your pain by circling the one number that best describes your pain at its ***least*** in the last week.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

5. Please rate your pain by circling the one number that best describes your pain on the ***average.***

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

6. Please rate your pain by circling the one number that tells how much pain you have ***right now.***

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

7. What treatments or medications are you receiving for your pain?

_____

8. In the last week, how much ***relief*** have pain treatments or medications provided? Please circle the one percentage that most shows how much *relief* you have received.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
No Relief										Complete Relief

9. Circle the one number that describes how much, during the past week, pain has ***interfered with*** your:

A. ***General Activity***

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

B. ***Mood***

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

C. ***Walking Ability***

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

D. ***Normal Work*** (includes both work outside the home and housework)

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

E. ***Relations with other people***

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

F. ***Sleep***

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

G. ***Enjoyment of life***

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

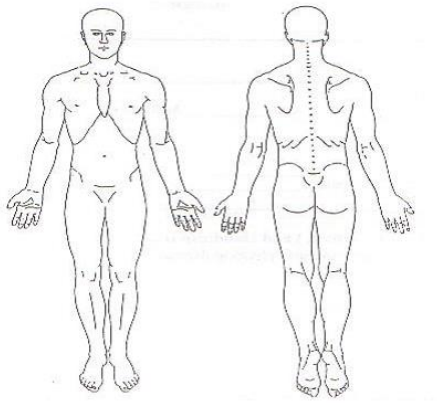
Scoring:
Pain Severity Score = Mean of items 3–6 (pain at its worst, pain at its least, average
Pain Interference Score = Mean of items 9A–9G (interference of pain with: general activity, mood, walking, normal work, relations, sleep, enjoyment of life)

Ukuhlolwa Kweengqaqamba (Brief Pain Inventory – Xhosa)	**Allocated no: _____** **Date: _____**

1. Kubomi bethu bonke, uninzi lwethu lube nokuqaqanjelwa (neentlungu), kumaxesha ngamaxesha (ezifana nentloko ebuhlungu ukukruneka, izinyo). Ukhe waqaqanjelwa ndaphandle kwezi ntlobo zengqaqambo kwisithuba seveki epheleleyo? Ukhe waneengqaaqmbo ezizezinye ngophandle kwezi zemihla ngemihla kule veki iphelileyo?

   Ewe Hayi

2. Kulo mfanekiso ulandelayo, zoba umthunzi kwiindawo apho uva iingqaqambo khona. Fakela uphawu X apho uva iingqaqambo kakhulu khona.



3. Nceda ulinganisele ukuqaqanjelwa kwakho ngokuthi urhangqe inani elithi lichaze ubungakanaini bengqaqambo ozivayo xa zikuphethe kakhulu kule veki iphelileyo.

0	1	2	3	4	5	6	7	8	9	10
Akukho zingqaqambo										lingqaqambo ezingako onokuthi uzithelekelele

4. Nceda linganisela iingqaqambo zakho ngokurhangqa inani elinye elichaza kakuhle iingqaqambo zakho xa zikuphethe kancinane kule veki idlulileyo.

0	1	2	3	4	5	6	7	8	9	10
Akukho zingqaqambo										lingqaqambo ezingako onokuthi uzithelekelele

5. Nceda ulinganisele ubungakanani beengqaqambo zakho ngokuthi urhangqe inani elinye elizichaza ngcono iingqaqambo zakho ngokomndilili.

0	1	2	3	4	5	6	7	8	9	10
Akukho zingqaqambo										lingqaqambo ezingako onokuthi uzithelekelele

6. Nceda linganisela iingqaqambo zakho ngokuthi urhangqe inani elinye elichaza ubungakanani bengqaqambo obuvayo ngoku.

0	1	2	3	4	5	6	7	8	9	10
Akukho zingqaqambo										lingqaqambo ezingako onokuthi uzithelekelele

7. Luluphi unyango okanye amayeza owasebenzisayo ukuphelisa iingqaqambo?

_____

8. Kule veki iphelileyo, ufumene isiqabu esingakanani kunyango okanye kumayeza owanikiweyo? Nceda rhangqa ipesenti ethi ibonise ubungakanani besiqabu osifumeneyo.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
Akukho siqabu										Isiqabu esipheleleyo

9. Rhangqa inani elinye elichaza indlela iingqaqambo ezithe kule veki idlulileyo zaphazamisana ngayo:
   A. ***Nokusebenza kwakho kwemihla ngemihla***

0	1	2	3	4	5	6	7	8	9	10
Azikhange zindiphazamise										Zindiphazamise ngokupheleleyo

   B. ***Nobume bomphefumlo***

0	1	2	3	4	5	6	7	8	9	10
Azikhange zindiphazamise										Zindiphazamise ngokupheleleyo

   C. ***Nekhono lokuhamba***

0	1	2	3	4	5	6	7	8	9	10
Azikhange zindiphazamise										Zindiphazamise ngokupheleleyo

   D. ***Nomsebenzi wesiqhelo*** *(kubandakanywa umsebenzi ongaphandle kwekhaya nowasendlwini)*

0	1	2	3	4	5	6	7	8	9	10
Azikhange zindiphazamise										Zindiphazamise ngokupheleleyo

   E. ***Nobudlelwana bam kunye nabanye abantu***

0	1	2	3	4	5	6	7	8	9	10
Azikhange zindiphazamise										Zindiphazamise ngokupheleleyo

   F. ***Nokulala***

0	1	2	3	4	5	6	7	8	9	10
Azikhange zindiphazamise										Zindiphazamise ngokupheleleyo

   G. ***Nokonwabela ubomi***

0	1	2	3	4	5	6	7	8	9	10
Azikhange zindiphazamise										Zindiphazamise ngokupheleleyo

Scoring:
Pain Severity Score = Mean of items 3–6 (pain at its worst, pain at its least, average pain)
Pain Interference Score = Mean of items 9A–9G (interference of pain with: general activity, mood, walking, normal work, relations, sleep, enjoyment of life)

Appendix C/2: Beck Depression Inventory English and Xhosa versions

Beck Depression Inventory - English	**Allocated no: _____** **Date: _____**

BECK'S DEPRESSION INVENTORY

In this questionnairre there are groups of statements. Please read each group carefully. Thereafter from the set choose one answer that describes best your feeling DURING THE PAST WEEK INCLUDING TODAY. Encircle the number of the answer you choose. If there are answers that are of equal importance encircle each one of them. Before making your choice make sure that you have read the statements thoroughly.

1. I do not feel sad. 0
   I feel sad. 1
   I am always sad and cannot change from this situation. 2
   I am very sad and it makes me unhappy that I cannot stand this. 3

2. I have not as yet been discouraged by a matter that pertains to the future. 0
   I feel discouraged by certain factors that pertain to the future. 1
   I do not feel like doing anything in life. 2
   I do not feel any hope for my future and nothing can change that. 3

3. I do not feel like a person who is unsuccessful. 0
   I feel I am the most unsuccessful person for a person of my age. 1
   When I look back in my life I only see failure. 2
   I feel I am a complete failure. 3

4. I find a lot of satisfaction in many things as usual. 0
   I do not enjoy things in the usual manner. 1
   I no longer get enough satisfaction in anything. 2
   I am not satisfied and I am tired of everything. 3

5. I do not feel guilty. 0
   I feel guilty most of the time. 1
   I feel guilty a great deal of the time. 2
   I feel guilty all the time. 3

6. I do not feel punished. 0
   I feel I being punished. 1
   I had expected to be punished. 2
   I feel punished. 3

7. I do not feel ashamed of being who I am. 0
   I feel ashamed of being who I am. 1
   I hate myself. 2
   Ndiyazicaphukela I detest myself. 3

8. I do not feel different (odd) from another person. 0
   I blame myself for my weaknesses or mistakes. 1
   I regret all the time about my mistakes. 2
   I regret all the time the bad thing that is happening. 3

9. I have no thoughts of committing suicide at all. 0
   I sometimes think of committing suicide but never do it. 1
   I would like to commit suicide. 2
   I can commit suicide if I can get a chance. 3

10. I no longer cry as I used to. 0
    I cry now a lot than I used to. 1
    I cry all the time. 2
    I used to be able to cry but I am now unable even when I want to. 3

11. I no longer get upset that much as I used to in the past. 0
    I get upset quickly and easily than before. 1
    I now feel upset all the time. 2
    I no longer get fully upset by what used to upset me before. 3

12. I have not yet lost interest in other people. 0
    I do not have a lot of interest in other people than before. 1
    I lost a lot of interest in other people. 2
    I lost interest completely in other people. 3

13. I still make a decision as I did before. 0
I postpone decision making more than I used to. 1
I experience great difficulty in making decisions than before. 2
I no longer know how tomtake decisions fully. 3

14. I do not find myself odd than usual. 0
I get worried over the fact tha I look old or attractive to people. 1
I feel there are permanent changes in my appearance that cause me not to be attractive . 2
I believe I am ugly. 3

15. I can work on anything like before. 0
It takes a lot of effort to start doing something. 1
In order to start doing something I must force myself. 2
I cannot do any work at all. 3

16. I can no longer sleep in the usual way. 0
I do not sleep in the usual way. 1
I wake up an hour to two before the time and it becomes difficult to sleep again. 2
I wake up a few hours before the usual time and it becomes difficult to sleep again. 3

17. I do not get more tired than usual. 0
I get tired quickly and easily than usual. 1
I get tired with almost everything I do. 2
I am too tired to do anything. 3

18. My appetite for food is not above normal. 0
My appetite for food is not normal. 1
My appetite for food is much worse now. 2
I have completely lost appetite for food. 3

19. I have lost weght lately, if there is any. 0
I have lost over 5 kilograms. 1
I have lost over 10 kilograms. 2
I have lost over 15 kilograms. 3
I am trying to lose weight deliberately by eating less. Yes / No

20. I no longer worry more than is normal about my health. 0
I now worry about physical problems like pains or an upset or windy stomach. 1
I am very worried about bodily problems and it is difficult to think about other things. 2
I am so worried about the problems of my body that I cannot think of something else. 3

21. I have not noticed any change in my sexual interest. 0
I have less interest in sex. 1
I have now very little interest in sex. 2
I have lost all interest in sex. 3

Uluhlu Locinzelelo Luka – Beck (Beck Depression Inventory –Xhosa)	**Allocated no: _____** **Date: _____**

ULUHLU LOCINZELELO LUKA-BECK

Kulo xwebhu lwemibuzo kukho amaqela eengxelo. Nceda funda iqela lengxelo ngalinye ngononophelo. Uze emva koko ukhethe ingxelo ibenye kwiqela ngalinye, echaza ngcono indlela ubuvakalelwa ngayo KWIVEKI EPHELILEYO, KUQUKA NANAMHLANJE. Rhangqela inombolo esecaleni kwengxelo oyikhethileyo. Ukuba kukho ingxelo eziliqela ekukhangeleka ngathi zifumaneka ngokulinganayo, rhangqela ingxelo nganye kuzo. Qinisekisa ukuba uzifundisisile kakuhle zonke ingxelo kwiqela ngalinye phambi kokuba ukhethe.

1. Andiziva ndilusizi. 0
   Ndiziva ndilusizi. 1
   Ndisolo ndilusizi amaxesha onke kwaye andikwazi ukuzikhupha kule meko. 2
   Ndilusizi kakhulu okanye ayindonwabisi into yokuba oku andikwazi ukumelana nako. 3

2. Andikatyhafiswa yinto ngokumayela nekamva. 0
   Ndiziva nditыhafiswa zizinto ezithile malunga nekamva. 1
   Ndiziva ndingenanto endijonge ukuyenza ebomini. 2
   Ndiziva ndingenathemba malunga nekamva lam kwaye akukho nto inokuguquka kulo nto. 3

3. Andiziva ndingumntu ongenempumelelo. 0
   Ndiziva ndingoyena mntu ungaphumelelanga ngakumbi kunomntu olingana nam. 1
   Xa ndijonga ngasemva ebomini bam, ndibona kuphela ukungabi nampumelelo. 2
   Ndiziva ndingumsileli ngokupheleleyo. 3

4. Ndiyalufumana ulwaneliseko oluninzi kangangoko kwizinto ezininzi njengesiqhelo. 0
   Andizonwabeli izinto njengesiqhelo. 1
   Andisafumani lwaneliseko lwaneleyo nasentwenina. 2
   Andonelisekanga kwaye ndidiniwe yinto yonke. 3

5. Andiziva ndinetyala. 0
   Ndiziva ndinetyala ixesha elininzi. 1
   Ndiziva ndinetyala inkoliso yexesha. 2
   Ndiziva ndinetyala ngalo lonke ixesha. 3

6. Andiziva ndisohlwaywa. 0
   Ndiva ngathi ndingohlwaywa. 1
   Bendikulindele ukohlwaywa. 2
   Ndiziva ndohlwayiwe. 3

7. Andiziva ndikudanele ukuba ndim. 0
   Ndiziva ndikudanele ukuba ndim. 1
   Ndiyazicekisa. 2
   Ndiyazicaphukela. 3

8. Andiziva ndibaxekile kunomnye umntu. 0
   Ndiyazigweba ngobuthathaka okanye ngeempazamo zam. 1
   Ndiyazisola ngalo lonke ixesha malunga neziphene zam. 2
   Ndiyazisola ngalo lonke ixesha malunga nento embi eyenzekayo. 3

9. Andinazicinga zokuzibulala kwaphela. 0
   Ndike ndicinge ngokuzibulala, kodwa ndingade ndikwenze oko. 1
   Ndingathanda ukuzibulala. 2
   Ndingazibulala ukuba ndinganalo ithuba. 3

10. Andisakhali njengesiqhelo. 0
    Ndikhala kakhulu ngoku kunesiqhelo. 1
    Ndikhala lonke ixesha . 2
    Ndandidla ngokwazi ukukhala, kodwa ngoku andisakwazi nkqu nokuba ndiyafuna. 3

11. Andisacutshukiswa kangako ngoku kunangaphambili. 0
    Ndicaphuka msinya nalula kunangaphambili. 1
    INdiziva ndicatshukisiwe ngalo lonke ixesha ngoku. 2
    IAndisacatshukiswa ngokuphelelyo zizinto ezazidla ngokundicaphikisa ngaphambili. 3

12. Andikalahlekelwa ngumdla kwabanye abantu. 0
    Andinamdla kakhulu kwabanye abantu kunangaphambili. 1
    Ndalahlekelwa ngumdla omkhulu kwabanye abantu. 2

Ndalahlekelwa nguwo wonke umdla kwabanye abantu. 3

13. Ndisasenza isigqibo ngohlobo endandidla ngokusenza ngalo. 0
Ndikubekela ecaleni ukwenza izigqibo ngaphezu kokuba ndandidla ngokuzenza. 1
Ndifumana ubunzima obukhulu bokwenza izigqibo kunangaphambili. 2
Andisakwazi ukwenza izigqibo ngokupheleleyo. 3

14. Andiziva ndibaxekile kunesiqhelo. 0
Ndiyakhathazeka yinto yokuba ndikhangeleka ndimdala kwaye ndingenamtsalane ebantwini. 1
Ndiva kukho iinguqu ezisisigxina kwimbonakalo yam ezindenza ndingabi namtsalane . 2
Ndiyakholelwa ukuba ndimbi. 3

15. Ndingasebenza nasentwenina njengangaphambili. 0
Kufuneka ndenze iinzame ezithe xhaxhe ukuze ndiqalise ngokwenza into. 1
Ukuze ndibe ndiyaqalisa ukwenza into kufuneka ndizinyanzele. 2
Andinako ukwenza nawuphina umsebenzi konke-konke. 3

16. Andisakwazi ukulala njengesiqhelo. 0
Andilali ngendlela yesiqhelo. 1
Ndifuka kwixesha elingaphambili ngeyure e-1 ukuya kwezi-2 kunesiqhelo kwaye kubanzima ukuphinda ndilale. 2
Ndifuka kwixesha elingaphambili ngeeyure eziliqela kunesiqhelo kwaye kubanzima ukuphinda ndilale. 3

17. Andidinwa kakhulu kunesiqhelo. 0
Ndidinwa msinya nalula kunesiqhelo. 1
Ndidinwa phantse yinto yonke endiyenzayo. 2
Ndidinwe kakhulu ukuba ndenze nantonina. 3

18. Umdla wam ekutyeni awubaxekanga kunesiqhelo. 0
Umdla wam ekutyeni awulunganga njengesiqhelo. 1
Umdla wam ekutyeni ubaxeke kakhulu ngoku. 2
Andisenawo umdla wokutya kwaphela. 3

19. Ndiphulukene nobunzima bam mva nje, ukuba bukhona. 0
Ndiphulukene nobunzima obungaphaya kweekilogram ezi-5. 1
Ndiphulukene nobunzima obungaphaya kweekilogram ezi-10. 2
Ndiphulukene nobunzima obungaphaya kweekilogram ezi-15. 3

Ndizama ukuphulukana nobunzima ngabom ngokuthi nditye kancinci.
Ewe / Hayi

20. Andisakhathazeki kakhulu ngoku ngempilo yam kunesiqhelo. 0
Ngoku ndikhathazeka kakhulu ngeengxaki zomzimba ezifana neentlungu okanye isisu esingamanga kakuhle okanye esiqunjelweyo. 1
Ndikhathezeke kakhulu zingxaki zomzimba kwaye kunzima ukuba ndicinge ngezinye. 2
Ndikhathazeke kakhulu gqitha zingxaki zomzomba wam kangangokuba andikwazi nokucinga ngenye into. 3

21. Andikaphawuli lutshintsho kumdla wam omalunga nendibano yesondo. 0
Andinamdla kakhulu kwindibano yesondo kunesiqhelo. 1
Mncinci kakhulu ngoku umdla wam kwndibano yesondo. 2
Ndiphulukene nomdla kwindibano yesondo ngokuphelelyo. 3

Appendix C/3: EQ-5D English and Xhosa versions

EQ - 5D

Health Questionnaire

South African English version

By placing a tick in one box in each group below, please indicate which statements best describe your own state of health TODAY.

Mobility

I have no problems in walking about	❑
I have some problems in walking about	❑
I am confined to bed	❑

Self-Care

I have no problems with self-care	❑
I have some problems washing or dressing myself	❑
I am unable to wash or dress myself	❑

Usual Activities (*e.g. work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities	❑
I have some problems with performing my usual activities	❑
I am unable to perform my usual activities	❑

Pain/Discomfort

I have no pain or discomfort	❑
I have moderate pain or discomfort	❑
I have extreme pain or discomfort	❑

Anxiety/Depression

I am not anxious or depressed	❑
I am moderately anxious or depressed	❑
I am extremely anxious or depressed	❑

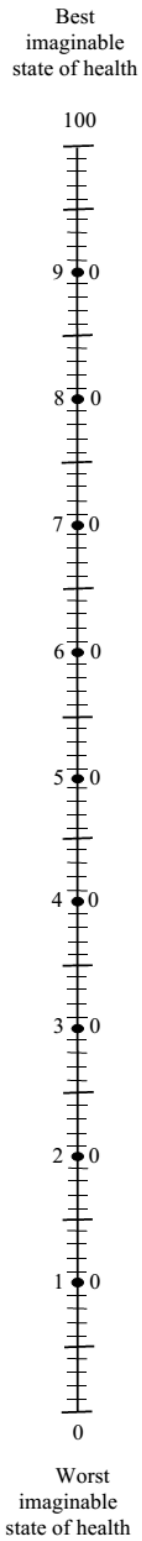
Compared with my general
level of health over the past 12 months,
my state of health today is:

Better	❑	PLEASE TICK
Much the same	❑	ONE
Worse	❑	BOX

To help people say how good or bad their state of health is, we have drawn a scale on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale, in your opinion, how good or bad your own health is today. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your state of health is today.

Your own state of health today



Because all replies are anonymous, it will help us to understand your answers better if we have a little background data from everyone, as covered in the following questions.

1. Have you experienced serious illness?

	Yes	No
yourself	❑	❑
in your family	❑	❑
while caring for others	❑	❑

PLEASE TICK APPROPRIATE BOXES

2. What is your age in years ? ☐

3. Are you male or female?

Male	Female
❑	❑

PLEASE TICK APPROPRIATE BOX

4.

I smoke	❑
I used to smoke	❑
I have never smoked	❑

PLEASE TICK APPROPRIATE BOX

5. Do you now, or did you ever, work in health services or social welfare?

Yes	No
❑	❑

If so, in what capacity? .....

PLEASE TICK APPROPRIATE BOX

6. Which of the following best describes your main activity?

self employed	❑
in formal employment	❑
retired	❑
homemaker/domestic worker	❑
student	❑
seeking work	❑
other (please specify)	❑ .....

7. What was the highest grade that you attained at school?

8. Do you have a diploma or equivalent?

Yes	No
❑	❑

PLEASE TICK APPROPRIATE BOX

9. If you know the area/suburb in which you stay, please write it here.....

EQ - 5D

Iphepha lemibuzo ngezempiio

(*Inguqulelo yesiXhosa saseMzantsi Afrika*)
(Xhosa version)

(best available)

Beka uphawu kwibhokisi ibenye kwiqela ngalinye echaza imeko yempilo yakho namhlanje, kwezi bhokisi zilandelayo.

Musa ukuphawula ngaphezulu kwebhokisi enye kwiqela ngalinye.

Ukuhamba

Andinangxaki zokuhamba ❑

Ndinazo ingxakana zokuhamba ❑

Ndingumlwelwe obopheleleke ebhedini ❑

Ukuzinonophela isiqu

Andinangxaki zokuzinonophela ❑

Ndinazo ingxakana zokuhlamba okanye ukuzinxibisa ❑

Andikwazi ukuzihlamba okanye ukuzinxibisa ❑

Izinto zesiqhelo (Umsebenzi, Ukufunda izifundo Umsebenzi wasekhaya, Usapho, Ezolonwabo)

Andinangxaki nokuzenzela izinto zesiqhelo ❑

Ndinazo iingxakana zokuzenzela izinto zesiqhelo ❑

Andikwazi kuzenzela izinto zesiqhelo ❑

Iintlungu / Ukungaziva kakuhle

Andinazintlungu okanye ukungaziva kakuhle ❑

Ndinentlungwana okanye ukungaziva kakuhle okungephi ❑

Ndinentlungu ezigqithileyo okanye ukungaziva kakuhle okugqithileyo ❑

Ukuxhalaba / Ukudakumba

Andinaxhala okanye andidakumbanga ❑

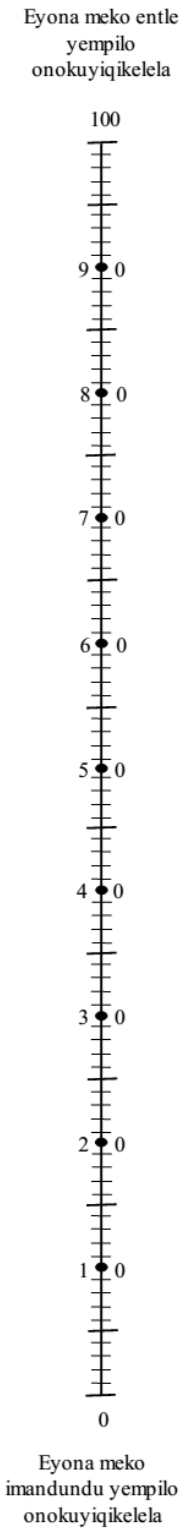
Ndibuxhalaba okanye ndibudakumba ❑

Ndixhalabe gqitha okanye ndidakumbe gqitha ❑

Ukunceda abantu ukuze baxele okokuba imeko yabo yempilo intle okanye imandundu na sizobe isikali (esifana nethemometha). Eyona meko entle yempilo iphawulwe ngo-100, eyona meko imandundu iphawulwe ngo-0.

Singathanda ubonise kwesi sikali ngokoluvo lwakho ukuba impilo yakho intle okanye imandundu kangakanani namhlanje.
Nceda wenze oku ngokuzoba umgca osuka ebhokisini engezantsi ukuya kulo ndawo esikalini ibonisa ukuba imeko yempilo yakho intle okanye imbi kangakanani namhlanje.

Imeko yempilo yakho namhlanje



Njemgoko kunganyanzelekanga ukuba ubhale igama lakho, kodwa ke kuyakunsinceda siqonde ngcono iimpemdulo ukuba sinolwazana lwemvelaphi kulowo nalowo umntu njengoko zichatshazelwe kule mibuzo ilandelayo

1. Ukhe wabanamava okugula kakhulu na?

	Ewe	Hayi	
Wena	❑	❑	Phawula iibhokisana ezifanelekileyo
Kusapho lwakho	❑	❑	
Xa ukhathalele abanye	❑	❑	

2. Mingaphi iminyaka yakho? [ ]

3. U-

Yindoda	Libhinqa	
❑	❑	Phawula ibhokisana efanelekileyo

4.

Uyatshaya	❑	Phawula ibhokisana efanelekileyo
Wawutshaya	❑	
Ungumntu ongazange atshaye	❑	

5. Usebenza, okanye ukhe wasebenza kwiinkonzo zezempilo okanye ezentlalontle?

Ewe	Hayi	
❑	❑	Phawula ibhokisana efanelekileyo

Ubusenzani? .....

6. Koku kulandelayo kokuphi okuchaza ngcono okwenzayo?

Uyaphangela okanye uyazisebenzela	❑	Phawula ibhokisana efanelekileyo
Udla umhlalaphantsi	❑	
Umsebenzi wasekhaya	❑	
Umfundi	❑	
Ufuna umsebenzi	❑	
Okunye (Chaza)	❑	

7. Leliphi ibanga ofikelele kulo esikolweni?……..

8. Unesidanga okanye i-diploma

Ewe	Hayi	
❑	❑	Phawula ibhokisana efanelekileyo

9. Ukuba uyayazi ikhowudi yeposi yakho nceda uyibhale apha [ ]

Appendix C/4: Self-efficacy for Managing Chronic Disease 6-Item Scale English and Xhosa versions

Self-Efficacy for Managing Chronic Disease 6-item Scale - English	Allocated no: _____ Date: _____

STANFORD PATIENT EDUCATION RESEARCH CENTER

We would like to know how confident you are in doing certain activities. For each of the following questions, please choose the number that corresponds to your confidence that you can do the tasks regularly at the present time.

1. How confident are you that you can keep the fatigue caused by your disease from interfering with the things you want to do?

not at all | | | | | | | | | | totally
confident 1 2 3 4 5 6 7 8 9 10 confident

2. How confident are you that you can keep the physical discomfort or pain of your disease from interfering with the things you want to do?

not at all | | | | | | | | | | totally
confident 1 2 3 4 5 6 7 8 9 10 confident

3. How confident are you that you can keep the emotional distress caused by your disease from interfering with the things you want to do?

not at all | | | | | | | | | | totally
confident 1 2 3 4 5 6 7 8 9 10 confident

4. How confident are you that you can keep any other symptoms or health problems you have from interfering with the things you want to do?

not at all | | | | | | | | | | totally
confident 1 2 3 4 5 6 7 8 9 10 confident

5. How confident are you that you can do the different tasks and activities needed to manage your health condition so as to reduce you need to see a doctor?

not at all | | | | | | | | | | totally
confident 1 2 3 4 5 6 7 8 9 10 confident

6. How confident are you that you can do things other than just taking medication to reduce how much you illness affects your everyday life?

not at all | | | | | | | | | | totally
confident 1 2 3 4 5 6 7 8 9 10 confident

Scoring

The score for each item is the number circled. If two consecutive numbers are circled, code the lower number (less self-efficacy). If the numbers are not consecutive, do not score the item. The score for the scale is the mean of the six items. If more than two items are missing, do not score the scale. Higher number indicates higher self-efficacy.

STANFORD PATIENT EDUCATION RESEARCH CENTER

Allocated No.:_____
Date: _____

Ubuchule onabo bokuLawula iSifo esingapheliyo isikali esinamabanga ama-6

Singathanda ukwazi ukuba uqiniseke kangakanani ekwenzeni izinto ezithile. Kumbuzo ngamnye kule ilandelayo, nceda ukhethe inani elithi lihambelane nokuqiniseka kwakho ngento yokuba unakho ukuzenza ezi zinto zilandelayo kumaxesha ngamaxesha.

1. Uqiniseke kangakanani ngento yokuba unakho ukulawula ukudinwa okubangelwa sisigulo sakho ekuphazamisaneni nezinto ofuna ukuzenza?

Andiqinisekanga konke konke | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Ndiqineseke gokupheleleyo

2. Uqiniseke kangakanani ngento yokuba unakho ukuthintela ubunzima obusemzimbeni okanye iingqaqambo zesigulo sakho ekuphazamisaneni nezinto ofuna ukuzenza?

Andiqinisekanga konke konke | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Ndiqineseke gokupheleleyo

3. Uqiniseke kangakanani ngento yokuba unakho ukuthintela ukuxhwaleka ngokwasemphefumlweni okubangelwa sisigulo sakho ekuphazamisaneni nezinto ofuna ukuzenza?

Andiqinisekanga konke konke | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Ndiqineseke gokupheleleyo

4. Uqiniseke kangakanani ngento yokuba unakho ukuthintela ezinye iimpawu okanye iingxaki zempilo onazo ekuphazamisaneni nezinto ofuna ukuzenza?

Andiqinisekanga konke konke | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Ndiqineseke gokupheleleyo

5. Uqiniseke kangakanani ngento yokuba unakho ukwenza imisebenzi edingekayo ukulawula ubume bempilo yakho ukulungiselela ukunciphisa isidingo sakho sokubonana nogqirha?

Andiqinisekanga konke konke | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Ndiqineseke gokupheleleyo

6. Uqiniseke kangakanani ngento yokuba unakho ukwenza izinto ngaphandle kokusebenzisa iyeza ukunciphisa ubungakanani bempembelelo yesigulo sakho kubomi bakho bemihla ngemihla?

Andiqinisekanga konke konke | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Ndiqineseke gokupheleleyo

Ukusikora:
Isikoro somba ngamnye linani elirhangqiweyo. Ukuba ngaba amanani amabini alandelelanayo athe arhangqwa, sebenzisa inani elisezantsi (ubuchule onabo obuphantsi). Ukuba ngaba amanani akalandelelani, sukuwanika iskoro. Isikoro sesikali ngumndilili wemiba emithandathu. Ukuba ngaba kukho imiba engaphezulu kwesibini ethe ayabikho, musa ukufaka isikoro kwisikali. Inani eliphezulu libonisa ubuchule onabo obuphakamileyo.

Appendix C/5: Physical performance task battery

Physical Performance Task Battery	**Allocated no: _____** **Date: _____**

1	**15 metres (m) walking at preferred speed.** For this test, subjects are timed as they walk 7.5m turn around, and walk back to the starting position at their preferred walking speed.	**Time:**
2	**15 m walk at fastest speed.** Subjects are again timed as they walk 7.5m, turn around, and walk back to the start as fast as they can.	**Time:**
3	**Unloaded forward reach.** For this test, subjects stand adjacent to a wall on which a tape measure is positioned horizontally at shoulder height. Subjects reach forward as far as they can and the distance reached is measured in centimetres (cm).	**Cm:**
4	**Timed, repeated sit-to-stand.** Subjects sit in a standard chair and are then timed as they stand up and then sit back down, twice. The test is repeated after a brief rest and the average time of the two trials is used.	**Time 1:** **Time 2:**

5	**Loaded forward reach.** For this test, subjects stand adjacent to a wall on which a tape measure is positioned horizontally at shoulder height. They hold a weighted bar (4.46 kg) with both hands close to their body and at shoulder height. They then reach forward as far as they can with the bar in a horizontal position, maintaining their hands at shoulder height. The reach distance is recorded in centimetres.	**Cm:**
6	**Timed, repeated reach-up.** For this test, subjects stand facing a wall and reach up as high as they can with both hands. A mark is placed on the wall at the reached distance. Subjects then reach up and return their hands to their sides three times, as fast as they can.	**Time:**
7	**Distance walked in 6 minutes.** Subjects walk as far and as fast as they can for 6 minutes. The distance walked is measured in metres at 6 minutes. (Subjects are allowed to rest if and as necessary during the 6-minute period.)	**Metres:**
8	**Timed belt tie.** Patients sit in a standard chair and are timed as they wrap a standard wrap bandage (approximately 1 meter long) around their waist and tie it in front of them.	**Time:**

Appendix D: The ‘Positive Living’ workbook

Positive Living

Name: _____

Positive Living

Welcome to “Positive Living”. This is a workbook designed to be used over 6 weeks which aims to help people develop self-management skills for living with HIV/AIDS. Using this workbook is not about sitting and reading or listening. In order to get the most out of this course you will be asked to share your experiences, you will need to set goals and share those goals with others and you will need to take part in activities. This workbook is NOT a substitute for any other medical care that has been recommended for the treatment of your condition.

You will benefit most from this workbook if you commit yourself to completing all the sessions within a 6 week period of time. Scientific research tells us that these courses are of great benefit to people living with chronic diseases such as diabetes, arthritis and HIV/AIDS. But to benefit from the course, using the workbook regularly over 6 weeks and participating in activities is essential. The workbook is divided into six sections:

1. Week 1: Self-management and Exercise
2. Week 2: Managing common symptoms of HIV/AIDS
3. Week 3: Stress Management
4. Week 4: Pain
5. Week 5: Eating Well
6. Week 6: Continuing as a successful self-manager

Your course leader is _____. She/he has been trained in all the information you will be going through. She/he has also been trained by a physiotherapist or occupational therapist who specializes in HIV/AIDS in safe ways to exercise and in relaxation techniques.

Week 1: Self-Management and Exercise

What do we mean by the term “self-management”? Self-management does not mean that you are expected to look after your health on your own with no help. No, someone who is a successful self-manager takes responsibility for their health. This means that they choose to work with the health team, with their drugs and with themselves to live a healthy life (just like a manager in a business – they don’t do everything themselves, they work with a team).

There are lots of things you can learn to do which will help you to be a successful self-manager. First of all it is important to understand HIV and AIDS. You need to understand about the virus and the disease, how it is transmitted, how it can affect you and about the medications used to treat it.

The next step in being a self-manager is being able to think about this information in terms of how it affects you. The final step in being a self-manager is to think about what it is that you want to be able to do, decide how you are going to do it and then to learn and practice the skills you need to be able to do it. Some of the things you will learn about and practice every day when you do this course include exercising, relaxation techniques and healthy eating.

Using this workbook you will learn about exercise and its benefits, in the second section you will learn a bit about the common symptoms of HIV/AIDS and how to manage these. The third section will focus on stress management, the final sections focus on pain, and eating well. Some people using this workbook may already know a lot about these topics, others may not know very much. It is important to share information and make sure that everyone has the knowledge they need to become a self-manager, even if you think you know a lot about these topics it is still worth your going through the workbook to make sure you have not missed out on any information. Scientific research tells us that people who are well informed about their health manage better and have a better quality of life. Using this workbook, you will also learn about and discuss the steps that are needed to become a good self-manager. Let’s look at these steps here.

Self-management steps

Step 1:

To be good at self-management you need to learn and practice several skills which you will practice through this course. The first step is to decide *what* it is you want to be able to do. This can be the hardest step to think about. For example you might be feeling very sad and depressed. First you need to think about why you are feeling that way. Perhaps one of the reasons you are feeling that way is that you have lost touch with your friends. Your first step might be to decide that you need to meet people to make friends. This will help you to feel less sad and depressed.

Write down here three things that you want to be able to do:

1) _____

_____

2) _____

_____

3) _____

_____

Step 2:

But deciding that you are going to meet people and make friends doesn't mean it will happen. You have to make it happen. The second step in being a self-manager is to decide *how* you are going to do it. Sometimes the thought of doing something new can seem too much and we don't even try. If you want to meet people to make friends you need to think about all the different options you have to do this. For example you could invite your neighbours for tea, or you could decide you would meet people by going to church, by joining a support group or an exercise group. Never assume that what you want to be able to do is impossible. Always look for every option and look at it from every angle.

Write down here three different ways that you could try to achieve what you want to do:

1) _____

2) _____

3) _____

Now that you have decided on *how* you can try to achieve what you *want*, you need to make an action plan. It is important that this plan is realistic otherwise it is likely you will not succeed. How do you do this?

- First decide what you are going to do *this week*
- Now make a *specific plan*

Saying that this week I'm going to try to meet some people is NOT a specific plan. To be specific, the plan must have different parts. It is useful to ask yourself some questions to help develop a specific plan. Questions like:

- *What?*

  Exactly what are you going to do? For example you could decide that to meet people you are going to invite your neighbour for tea.

- *How much?*

  Then you must decide how much you are going to do. For example are you going to invite one neighbour for tea or are you going to invite lots of neighbours over. Lots of people are much more tiring than one person. Or do you want to invite your neighbour for lunch? But lunch means a lot more preparation and time and will make you more tired. So you have to decide how much you can do.

- *When will you do it?*

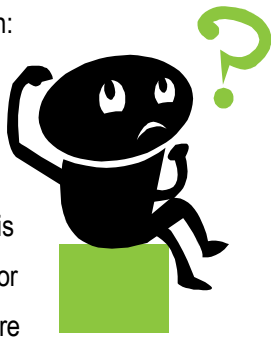
  Then you must decide on exactly which day you are going to do the activity and at what time of the day. Maybe it is better to invite your neighbour for tea in the morning because you get tired in the afternoon. Or if you feel sick in the morning from your medicines maybe it is better to invite your neighbour for afternoon tea. Or maybe your neighbour works and you need to invite them for tea at the weekend.

- *How often?*

  This is always the hardest part. We all would like to be able to do more things every day. But we are human and this is not always possible. When people want to start exercising, we often say we are going to do it every day. But this is often just not possible and if we then miss a day we feel that we have failed and we give up. How often will you invite your neighbour for tea? Not every day but maybe once a week. You know that you won't become friends immediately and that it will take time.

- *Is it a good plan?*

  To test whether you have come up with a good plan you need to ask yourself this question:
  "*If I give myself a score from 0 -10 for how confident I am that I will achieve my plan this week, where 0 is not at all confident, and 10 is totally confident. What score will I give to show how confident I am that I can complete this plan?*"

  If your answer is 7 or more out of 10 then this is probably a very good plan. If your score is less than 7 you need to think about why you are not confident. What are the problems or barriers? Can you change the plan or solve the problems to make yourself feel more confident?

Step 3:

Now, write your plan down and put it somewhere you will see it every day. There is an action plan form at the end of this section and 5 more at the back of this book. Use them every week you are doing this course. You can always draw more of them to keep working on your plans in the future.

A good action plan is:

- Something I want to do
- Something I can expect to do this week
- Is specific
- Answers the questions: What? How much? When? How often?
- I am confident that I can achieve with a score of at least 7 out of 10.

Now you need to carry out your action plan. If it is a good plan then doing it is usually fairly easy. It helps to tell family or friends what your plan is and to report back to them on how you are doing. On this course you are going to make a plan every week and record how you get on. It helps to report back on things because you can then have an idea on how well you are doing. If you haven't been able to keep to the plan you can discuss the problems you might have had and make plans to cope with them.

Step 4:

Always check your results and give yourself a reward for having achieved your plan. Also think about how achieving your plan is making you feel. In the example we talked about, you could congratulate yourself for having invited your neighbour for tea, you would also think about how you now feel. Is the plan helping you to achieve what you want?

What about problems?

What if your plan doesn't work? Are you going to give up and decide you had a bad plan? There are seven steps to solving problems. These are:

1. Deciding what the problem is (you might need friends and family to help here)
2. List ideas to solve the problem
3. Select one idea to try
4. How did it go?
5. If it didn't work, try another idea
6. If your ideas don't work, ask friends, family, counsellors, professionals for ideas
7. Finally you might have to accept that you can't solve the problem now.

A successful self-manager is someone who:

- Sets goals
- Makes a list of ways to achieve those goals
- Makes action plans to achieve the goals
- Carries out the action plans
- Checks on their progress every week
- Can change the action plan if there are problems
- Gives themselves a reward for achieving their goals

At the end of each section and at the back of the workbook there are “Action Plan Forms”. Use these forms to plan what you want to do and how you are going to do it. We are now going to discuss exercise – use the “Action Plan Form” at the end of this section to plan what exercise you are going to do this week.

Exercise

Exercise is a very important way to keep healthy. Scientific research tells us that exercise has a lot of good effects on our bodies like helping our digestive system absorb and process food; it trains our hearts so that they are strong and healthy and keeps our lungs working well. Exercise makes our muscles and bones strong and our joints flexible so that we can keep moving. Exercise also helps to make us feel happy, improves concentration and memory, improves sleep and exercise helps to decrease the chances of developing chronic illnesses like high blood pressure and cancers.

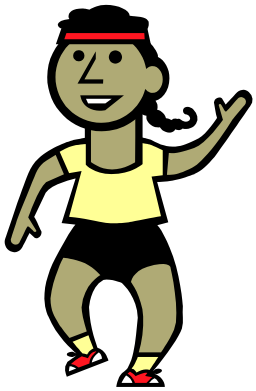
In the past, when people became ill with a chronic illness like high blood pressure or diabetes or HIV/AIDS, medical care focused on helping them when their symptoms became worse. Treatment focused on using drugs and people were often advised to rest or decrease their activity. Today we know that if we teach people who develop chronic illnesses about their disease and encourage them to do exercise we can prevent a lot of the problems which used to be treated with medicines. We also know that exercise can help to treat a lot of the symptoms which people with chronic diseases develop. Symptoms which may be caused by the disease or by the drugs used to treat the disease.

You may be wondering if it is safe for you to exercise when you have an illness like HIV/AIDS. Research tells us that ***it is safe for people living with HIV/AIDS to do exercise***. Not only is it safe, it also stimulates the immune system, improves endurance and decreases fatigue, improves strength and decreases body fat. We also know that strengthening exercises seem to help prevent or decrease lipodsytrophy in people who are taking ARVs (Lipodystrophy means that your body stops storing fat in places where it normally stored it - like in your buttocks, and begins to store the fat in places like your chest or your stomach). We know that people who are physically fit get fewer colds and take fewer days off work because of illness. One of the biggest benefits of exercise is that exercising regularly makes you feel more in control of your life.

Although exercise is good for you and safe for you to do, sometimes your body will give you clues that you need to cancel your exercise. If you have a fever, feel dizzy, have vomiting or diarrhoea, if your joints have suddenly become swollen, or if you have a pain which is new and you are not sure what is causing it, it is better to miss an exercise session until you can speak to a nurse or doctor.

Exercise is good for:

- Improving mood
- Strength
- Improving sleep
- Concentration and memory
- Heart and lung health
- Decreasing body fat
- Digestion
- Increasing confidence to self-manage chronic illness.



Do not exercise if:

- You have a fever
- You are dizzy
- You have been vomiting
- You have diarrhoea
- Your joints have suddenly become swollen
- You have a new pain which you don't know the cause of

Miss one exercise session if you have one of these problems until you can speak to a nurse or doctor. This does not mean you should never exercise but you need to make sure you are not becoming ill.

What kind of exercise should you do?

You do not have to join a gym or a club to get exercise. There are lots of ways of exercising from formal sports like running, playing football or netball, swimming or playing tennis. But, walking is also a very good way to exercise. Any activity which makes your heart beat faster and makes you breathe a little harder is exercise. Dancing is exercise, walking up the stairs is exercise, gardening is exercise. There are lots of ways that we can exercise every day without having to go to a class or join a club. You could walk a little further before catching the bus or the taxi or you could play with your children!

There are three general kinds of exercise you can do. Endurance exercise; like walking, running, dancing or swimming. Endurance exercise is sometimes called aerobic exercise which means that you will be breathing faster and your heart will be beating faster too. We know that this kind of exercise is very important to keep healthy and we need to do 30 minutes of this kind of exercise three times a week to keep healthy. The second kind of exercise is strengthening exercise. This kind of exercise focuses on making us stronger. To make muscles stronger we have to do exercises which make the muscles work hard against a resistance, like weight training but you can also do strength training by working with heavy bags of shopping! The last kind of exercise is stretching exercise. Stretching exercises focus on keeping us mobile and flexible.

Types of exercise:

- Endurance exercise which makes you breathe harder (sometimes called aerobic)
- Strengthening exercise which makes you stronger
- Stretching or flexibility exercise which makes you more mobile and supple

Endurance

Strengthening

Flexibility

There is an extra reason for people living with HIV/AIDS to do strengthening exercise. Scientific research tells us that strengthening exercises seem to help to prevent or limit lipodystrophy. Lipodystrophy means that your body stops storing fat in places where it normally stored it (like in your buttocks) and begins to store the fat in places like your chest or your stomach. Lipodystrophy doesn't just change the shape of the body, we also know that people who develop lipodystrophy tend to have high cholesterol and low insulin meaning that there is a bigger chance that they will have heart problems or develop diabetes. The exact cause of lipodystrophy is not clear but it seems to occur with certain HIV drugs, in older people and in people with a low T cell count who have been HIV+ for a long time. The most recent research tells us that if you do weight training (which builds up more muscle) you can limit lipodystrophy. This is a very good reason to make sure you do strengthening exercises in your exercise routine.

We know one of the hardest things about exercise is not doing it once, but doing it again and again. There are several steps we can follow to make sure that when we start to exercise we stick to it. We all make lots of excuses why we can't exercise. Let's look at the most common excuses.

"I don't have time"

It doesn't take a lot of time to start exercising. Five minutes a day is a good start. We make time to take medicine because we know without it we would become ill. Exercise is as important as medicine to help us remain healthy (remember it can never replace your drugs). If we know that it is that important we can make time for it.

"I'm too tired"

When people become ill they often become less active. As you become less active, your body loses fitness and you become weaker, you may feel stiffer and you tire more easily. This means that exercising might feel harder and so you exercise less. This often results in a downward spiral of activity and people often get to the point where even walking down the street to visit the neighbour can feel like too much. Being active or doing exercise when you are feeling tired will give you more energy and make you feel less tired.

"I'm too sick"

You may be too sick to undertake very vigorous exercise but you can still aim to be more active. You can even break your exercise into one minute sessions which you repeat several times through your day. The fitter you get, the better you will be able to cope with your illness

"I get enough exercise already"

You may be getting a lot of exercise already in your job or simply walking around doing your daily chores. But for most people if we add this time up, it still isn't enough exercise to keep them fully fit. This kind of exercise also doesn't include one of the most important components that make exercise good for us – fun!

"Exercise is boring"

You don't have to do the exercises that everyone else does if they are boring. Choose something that is fun, exercise with a friend or with your favourite music or listen to the radio. You can also keep your exercises fun by changing them regularly.

"Exercise is painful"

Exercise may be uncomfortable but it shouldn't be painful. If you have pain before you start to exercise, it should not get worse while you are exercising. If you do not have pain before you start to exercise and you start to feel pain while you exercise you need to stop exercising and evaluate your pain using the guidelines in Week 4: Pain. If you have muscle or joint pain for more than two hours after you exercise then you have probably done too much. Next time do a little less, either exercise for less time or less vigorously.

"It's too dangerous, it's too hot, it's too cold"

There are always reasons like this not to exercise. Remember that exercise can be done anywhere and anytime. You can put on music in your home and dance, if its too hot you could walk around shops which have air-conditioning. Finding a group of people to exercise with will not only make it safer but also more fun!

"I know I won't stick to it so there is no point in starting"

First review the steps we discussed on how to be a successful self-manager. If you set your exercise goals using these steps you have more chance of sticking to your exercises. Remember too the important step of rewarding yourself for achieving your goals, this makes it easier to move on to your next goal. We are now going to have a look at the important steps to take to be successful at putting your exercise plan into action.

Steps to success with exercise:

- Set a clear goal using the steps outlined in "How to be a successful self-manager"
- Choose exercise or activity that you want to do and that is fun
- Set a specific time and place to do your exercise
- Decide how long you are going to stick to the plan before you think about changing it (6 to 8 weeks is a good time to work on things)
- Keep an exercise diary to keep track of how you are doing (there is one at the back of this booklet for you to use)
- Keep track of your progress using the exercise diaries in this workbook.
- Start – don't wait, start now. Begin gradually and proceed slowly
- Revise your programme. At the end of the 6 – 8 weeks make a new plan for the next 6 weeks
- Reward yourself. It is a reward to feel better and healthier but also give yourself a reward for achieving your goal, like eating a favourite meal, or visiting a friend or taking a walk somewhere special.

Your exercise programme:

An exercise programme should include the three different types of exercise; remember they were endurance, flexibility and strength exercise. Following the steps in the box "Steps to success with exercise", you need to decide on what you want to be able to do and what exercise you would like to do. Now that you know what exercise you are going to do, you need to decide how much to do. The amount of exercise you are going to begin with will depend on a lot of different things. If you have not done any exercise for a long time or have been feeling unwell, have had difficulty breathing or been short of breath, if you have had stiffness or pain or weakness that interferes with your daily activities then you need to start your exercise slowly. You can begin slowly by starting with some flexibility and strengthening exercises. Do these exercises every other day for 5 minutes. Once you can do that comfortably and without feeling stiff or sore the next day, increase it to 10 minutes. Once you can do 10 minutes comfortably, you can start doing the exercises every day (when we say exercise every day, we usually mean exercise for 5 days of the week; it can be very hard to keep a routine to exercise on weekends when activities are different). Once you can do at least 10 minutes every day then you are ready to begin endurance exercises. Choose your exercises from the ones set out in the sections below. Follow the instructions in the box to make sure you get the most out of the exercises and do them safely.

Getting the most out of your flexibility and strength exercises:

- Move slowly and gently. *Do not* use jerking or bouncing movements as these will make your muscles shorter and tighter.
- Stretch to the point of *tension* in a muscle and hold for 20 seconds before you relax
- Don't push until it hurts, *stretch to tension not pain*
- Start off with 5 repetitions of each exercise. After 1 week increase it to 7, after another week increase to 10.
- Always do the *same number* of exercises on the left side and the right side of your body
- *Keep breathing*; do not hold your breath when you exercise. Think about breathing out as you move to make sure you do not hold your breath.
- Use the *two hour rule*. If you have increased symptoms for more than two hours after you exercise you have probably done too much. Don't stop doing the exercises but decrease how much you do next time.
- If you find an exercise difficult this does not mean you should not do it at all. You should adapt it, do it as completely as you can.

Flexibility Exercises:

Remember, these exercises are aimed at improving your ability to move. There is a long list of exercises that could be included here and you might not be able to do them all every time you exercise. Try to ensure that you do flexibility exercises at least once a week.

Strengthening Exercises:

You do not need to go to a gym to do strength exercises, the exercises described here can be done at home. To make muscles stronger you must make them work against a resistance or a force – they have to push or pull. You should not do strength exercises every day, rather they should be done every second day. Your muscles need a day of rest to adapt and get stronger. To make a muscle stronger you need to repeat each exercise 5 times to start with. Once you can do an exercise 10 times you will not get stronger by doing more exercises. Now you will need to add more resistance to the exercise to get stronger.

Endurance Exercises:

The most difficult thing for most people is deciding how much exercise to start with. The easiest starting point is to ask yourself the question: "how much do I think I can do without suffering for it tomorrow?" If you feel you can do 5 minutes, then do 5 minutes. Remember that any exercise is better than none. You don't have to do 30 minutes from the first day. It is important to start slowly and increase very gradually. It is better to start off by doing less than you think you can and increase it from there.

There are three things you need to think about when you do endurance exercise. These three things are *frequency* (how often am I going to do this exercise); *duration* (how long am I going to exercise for when I do exercise) and *intensity* (how hard am I going to work when I exercise).

Frequency:

Try to do endurance exercise 3 or 4 times a week. By doing this you can rest every second day and allow your body to recover. All athletes have at least one day a week when they rest. Rest does not mean that they lie in bed all day though, it means that they do not do their exercises.

Duration:

How much can I do without suffering for it tomorrow? That is your starting point. If you are starting with just a few minutes you can gradually increase it over time until you can do 30 minutes at a time. The easiest way to increase the time is to use intervals of exercise. For example to walk hard for 3 minutes, then walk slowly for 2 minutes, then walk hard again for another 3 minutes. Slowly over time cut down the slow walking and increase the hard walking. You could also break your exercise into separate sessions. You could walk for 10 or 15 minutes in the morning and do it again in the evening. This would still count as 30 minutes of exercise.

Intensity:

How will you know that you are exercising hard enough to be doing some good? How will you know if you are exercising too hard? When doing endurance exercise the easiest way to check the intensity is to use the "Talk Test". When you are doing moderate intensity exercise you should be able to talk comfortably but if you tried to sing it would be a little difficult and you would have to stop singing to take bigger breaths. Moderate intensity means you should feel that you are breathing a little faster and a little harder but you can still talk. It may take you a while to find the right intensity for you for the whole of your exercise session. This is normal; take your time to get to know how your body will respond.

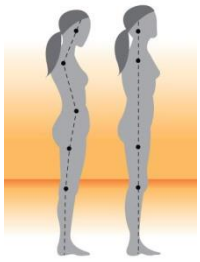
How will you know you are improving in your exercises? For the flexibility and strength exercises it is easy to feel the improvements as you will feel that moving is easier and you are stronger and can lift heavier items. For some people it is harder to know if you are improving with the endurance exercises. One way to see if you are improving is to do a test. One of the easiest tests to do is a timed test. Decide on a route that you can walk near your home. Walk this route at a moderate intensity and time how long it takes. After several weeks of exercise walk the route again and time it again. You may see that you can walk the same route faster within 4 weeks, but it may take 8 to 12 weeks before you see that you can do the route in a faster time. The goal is to complete the same route faster or in the same time but at a lower intensity (breathing much easier).

Use the exercise diary at the end of each section to record your goals and your progress in achieving them.

Exercise Routine

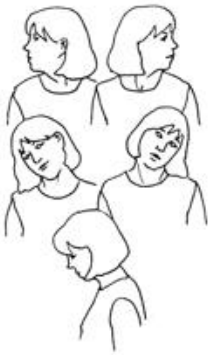
This is a 20 minute exercise routine which is safe for people living with HIV. This routine includes exercises which make you stronger (strength exercises), more flexible (stretching exercises) and fitter (endurance exercises).

1. Start by standing up straight and tall, feel your weight across your feet, relax your shoulders and open your chest, hold your head straight. Take a deep breath in and breathe out.



2. March on the spot for 2 minutes. March at a steady pace – that is a pace which you can maintain for 2 minutes. Do not start fast and get slower or start slowly and get faster. Pace yourself, start and finish at the same speed. You should be marching so that you can feel you are breathing a little bit harder than normal, you should be able to talk but not be able to sing.

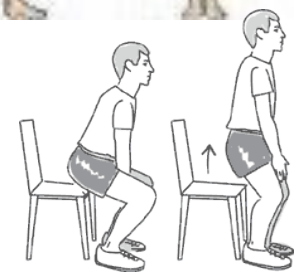
3. Now stretch your neck – keep your shoulders relaxed and turn to look over your right shoulder – hold it for 20 seconds. Bring your head back to the middle, then turn to look over your left shoulder – hold it for 20 seconds and then bring your head back to the middle. Now put your left ear on your left shoulder - hold it for 20 seconds and then bring your head back to the middle. Repeat to the right. Now put your chin on your chest - hold it for 20 seconds and then bring your head back to the middle. Roll shoulders forwards 5 times, then roll your shoulders backwards 5 times.



4. March on the spot for 2 minutes – 30 steps normal, 30 steps lift your knees up as high as you can. Keep changing every 30 steps.

5. Stretch your body – with your feet shoulder width apart, slide your right hand down your right leg so that you bend sideways. Bend as far as you can - hold it for 20 seconds and then stand up straight again. Repeat this to the left. Put your hands on your bottom; bend your body backwards as far as you can. Now bend forward and try to touch your toes.

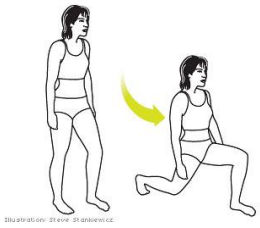
6. Sit on a chair – now stand up, keep sitting down and standing up for 2 minutes. Stand up and sit down at a steady pace – that is a pace which you can maintain for 2 minutes. Do not start fast and get slower or start slowly and get faster. Pace yourself, start and finish at the same speed.



7. Lie down on the floor with your knees bent and your arms crossed on your chest. Lift your head to put your chin on your chest, now lift your shoulders off the ground. Slowly lower down. Keep going for 2 minutes.

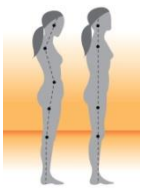
8. March on the spot for 2 minutes – 30 steps normal, 30 steps lift your feet up as high as you can (try to kick your buttocks). Keep changing every 30 steps.

9. Stand up straight. Take one big step forward with your right foot and bend your knees so that your left knee almost touches the ground (lunge). Push back with your right leg to bring your feet back together again. Repeat on the left. Do 10 lunges on each leg.



10. March on the spot for 2 minutes – 30 steps normal, 30 steps lift your knees up as high as you can. Keep changing every 30 steps.

Finish by standing up straight and tall, feel your weight across your feet, relax your shoulders and open your chest, hold your head straight. Take a deep breath in and breathe out.



Action Plan Form - Exercise

Use this form to develop an action plan on exercise. What exercise would you like to do?

Be sure your action plan includes:

What you want to do

How much you are going to do

When you are going to do it

How many days a week you are going to do it

For example: This week, I will walk (*what*) around the block (*how much*) before lunch (*when*) three times (*how many*).

This week I will:

_____*(what)*

_____*(how much)*

_____*(when)*

_____*(how many?)*

How confident are you that you can complete this action plan?

Not at all confident										Totally confident
1	2	3	4	5	6	7	8	9	10	

Keep a record of how you did:

	I Plan to…..	**I did…..**
Monday		
Tuesday		
Wednesday		
Thursday		
Friday		
Saturday		
Sunday		

Week 2: Managing Common Symptoms of HIV

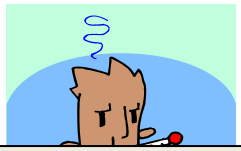
When something that is happening to our bodies that is unusual or not right, we develop symptoms. Symptoms include things like having a fever or temperature, feeling nauseous, vomiting, feeling tired, having pain, having a skin rash, coughing or struggling to breathe, feeling depressed and many, many more. People living with HIV/AIDS are likely to have many different symptoms which need to be managed. In this section, you will learn about *some* of the more common symptoms which people living with HIV/AIDS experience. You will also learn how to manage these symptoms. If you start feeling a symptom which is not described in this section then it is best for you to go to your clinic to get your symptom checked by a doctor or nurse.

The symptoms that people living with HIV/AIDS get can be put into one of three groups. The symptoms may be a side-effect of the medicines that you are using. Information on the side-effects of medicines can be obtained from your clinic and from other support and treatment literacy groups such as the Treatment Action Campaign (TAC). The second possible cause of symptoms is HIV-related infections. You might have a cough because you have developed pneumonia or TB. The third possible cause of symptoms may be the HIV itself. People with chronic illnesses like diabetes, high blood pressure, arthritis and HIV will all get symptoms related to the illness. These symptoms tend to increase and decrease over time. Research tells us that all symptoms can be managed better by following a good programme for living well as using the steps described in this workbook.

Symptom Management

All of the different activities described in this workbook will help you to live well and manage different symptoms. Exercise, eating well, using relaxation techniques and managing stress are all important to help prevent new symptoms from developing. Before we go through the most common symptoms which people with HIV/AIDS experience, there are a few principles to keep in mind when you experience a new symptom. If it is a new symptom, it could be a sign that you are developing an infection or it might be a side effect of a drug. Use the information in this section to help you decide on what action you need to take for the new symptom. It might be something that is safe for you to manage to home, or it might be something that you need to go to the clinic for, or you might manage at home for a while but if it doesn't get better then go to the clinic. Use the charts in this section to help you decide on how to deal with some of your symptoms

If you start experiencing a symptom you need to take time to think about it. Is this a new symptom, one you have experienced before or a symptom you have had for a while which is getting worse? You can do a FAST check (as described in the box below) on any new or worsening symptoms.



FAST check for new or worsening symptoms:

Fever	Do you also have a fever which started with the new symptom? (temperature of more than 38°C)	Having a temperature or fever can be a chronic symptom of HIV/AIDS. But if a fever starts with another symptom it can be an important clue that you have developed an infection.
Altered mental status	Have you also noticed a change in your mental state with the new symptom?	The brain is a very sensitive part of the body. Altered mental status is the term used to describe feeling confused, dizzy, and very sleepy. It can also mean more severe problems like coma or experiencing seizures or fits. You may need your friends or family to help you assess this.
Severe	Is this symptom much more severe (worse) than anything you have had before?	Symptoms come and go but if it is much worse than ever before you need to have it checked.
Typical	Is this symptom not typical for you?	Anything that is totally new and you have never had before, it is best to discuss it with a health care practitioner. You can use the charts in this workbook to decide whether you need to go to the clinic immediately or if you can wait until your next planned visit.

Once you have done your FAST check you can then use the action charts in this section to help you decide what to do next. When you read the action charts, you need to start at the top and follow the arrows depending on your answers to the questions. Do not jump around the chart as this will lead to mistakes. You will see on the chart that some symptoms mean that you need to go to your clinic straight away (now), some symptoms you need to go to the clinic today, and some symptoms you can manage yourself at home until your next routine clinic appointment. If you have more than one symptom, check the charts for all the symptoms and follow the most conservative (safest) advice. If your symptom is not described in this workbook then go to the clinic today to get it properly assessed. We will now discuss some of the symptoms in alphabetical order.

Breathing problems and coughing

Your body uses coughing to protect your lungs and to remove abnormal things from your lungs. Anything that irritates your lungs can cause you to cough. Coughing might bring up infected pus or mucous from the lungs which is useful. Coughing can be a side effect of medication used for high blood pressure too.

Smoking is one of the most common causes of coughing as the smoke kills cells in the breathing tubes to the lungs. This can happen even in people who are not smoking themselves but are breathing in other people's smoke. Other common causes of coughing are "colds" and "flu" which often cause yellow or white mucous.

Infections of the sinuses (the passages of the nose), can cause coughing because the mucous drips down from the back of the nose into the throat and lungs which irritates them and makes you cough. This is usually worse at night. Another common cause of coughing is hay fever. Hay fever is more common in spring and when it is windy. Dust from tree flowers (pollen) and plant seeds in the air make it worse. If you are coughing because of hay fever, you will also have either itchy, red eyes and / or a bit of a sore throat with sneezing. The clinic can provide you with anti-histamine medicine to help with this.

Cough Action Chart:

Are you also short of breath at rest or short of breath with walking around?	Yes →	Go to the clinic now
No ↓		
Is your cough dry and do you also have a fever?	Yes →	Go to the clinic today
No ↓		
Do you also have a fever and pain in your chest with your cough?	Yes →	Go to the clinic today
No ↓		
When you cough do you cough up thick, bad-smelling brown or green mucous?	Yes →	Go to the clinic today
No ↓		
Have you had a fever for more than 4 days or has your cough lasted for more than 10 days?	Yes →	Go to the clinic
No ↓		
Treat your cough at home		

People living with HIV/AIDS are also vulnerable to developing lung diseases which cause coughing. The first serious cause of coughing in people living with HIV/AIDS is TB. Tuberculosis of the lungs (TB) causes a cough which lasts a long time with a fever. If you have a cough which lasts for ***more than 10 days*** then TB should be suspected and you should go to the clinic. The second serious cause is *Pneumocystis* pneumonia (PCP). PCP causes a dry cough (there is no mucous) with a fever and shortness of breath. Take a look at the "cough action chart" and you will see that any cough that also has a fever means you need to go to the clinic straight away.

Home treatment for a cough: You can treat your cough at home by making sure you are not dehydrated. If you do not have enough fluid in your body it will make the mucous in your lungs dry and sticky and more difficult to cough out. Drinking a lot of water will help with this. If you have a shower then having a hot steamy shower may also help, or steaming with hot water or rooibos tea will help. If you have a dry cough with tickling in your throat, it may help to suck on cough lozenges or on a hard sweet.

Depression:

It is common for people living with HIV/AIDS to become depressed but this is often not picked up by the nurses and doctors at the clinic. It is important for you to tell your nurse or doctor if you think you have depression. Depression is an illness, it is not simply the shock, scared, lonely and stressed feelings you probably experienced when you first heard your HIV status. Those feelings are a normal reaction to learning about your status. Depression develops over a few weeks and is a general feeling of depressed mood which happens with physical symptoms. This is caused by an imbalance of chemicals in the brain. See the depression checklist below – if you think you have depression and you have many of these symptoms then you probably have some degree of depression. This can be treated with medicine and psychological support. It is not something to be ashamed of. Go to the clinic and tell the nurse or doctor how you are feeling so that they cans start you on treatment.

Dementia is very different from depression. With dementia your thinking is affected so that you struggle to communicate, you may struggle to pay attention and forget things a lot. You may also find it hard to move, be clumsy, lose your balance or even find that you can't move at all (paralysed). Your personality might also change. People who develop dementia generally do not feel depressed as they are usually not aware that they are unwell. Dementia is treated with ARV's.

Depression Check List:

- Do you feel down most of the time?
- Do you lack enjoyment with fun things like music, soccer or chocolate?
- Do you try to find peace by overeating?
- Or do you lack appetite and lose weight?
- Do you sleep badly at night?
- Do you struggle to get up in the mornings?
- Do you feel angry and agitated very quickly?
- Do you feel very passive?
- Do you lack energy every day?
- Do you struggle to concentrate?
- Is it difficult to make decisions about simple matters?
- Do you feel guilty?
- Do you feel worthless sometimes?
- Do you think of death a lot?
- Do you think of killing yourself?

If you answer yes to <u>many</u> of these questions, then you may have some degree of depression. Speak to the doctor or nurse at the clinic about how you are feeling.

If you answer yes to one or two of these questions then you may have depressed mood which you can manage with some of the techniques described in the section on stress

Home treatment for Depression: There are many things you can do to help manage depression. Make sure that you get help straight away if you *feel like hurting yourself or someone else*. Often talking to a person who understand or to a health professional will help you through this mood. *Cut back on alcohol*, although it might make you feel better in the short term. In the long term it affects the way your brain works and you will not be able to escape the depression. *Keep active,* make you sure you get up every day, get dressed and get out of the house. Even if you don't feel like doing things, it's important to keep active, visit friends, and join a group. If you start to lose contact with people and withdraw your mood will only get worse. Make *plans for the future*, for tomorrow, for next week, for next month. Make sure you do *20 to 30 minutes of exercise* every day. As we said in Week 1, exercise is very important to keep us healthy and help our moods. Depression feeds on depression, when you believe that things will get better, they will start to change. Use the suggestions in the section on Week 3: Stress Management to help you manage your symptoms.

Diarrhoea (Running tummy)

Diarrhoea can affect anyone. Diarrhoea means you have to go to the toilet often and / or your stool is watery or slimy. Sometimes diarrhoea comes with stomach pains or with vomiting or both. When you have diarrhoea your body is losing water all the time. Losing water is called dehydration and can be dangerous, especially for children.

Diarrhoea can be because of infections, as a side effect of medicines or caused by poor absorption of food. Diarrhoea can be prevented by making sure that you are using clean drinking water, that you prepare food carefully (see the section for Week 5) and make sure that you wash your hands every time after going to the toilet.

Diarrhoea Action Chart:

Do you have?

- *Black or bloody stools*
- *Severe, steady stomach pain*

Yes → Go to the clinic now

No ↓

Do you have any signs of dehydration?

- *Extreme thirst*
- *Very dry mouth*
- *Dark urine*
- *Lightheadedness*

Yes → Go to the clinic today

No ↓

Are you taking antibiotics?

Yes → Go to the clinic

No ↓

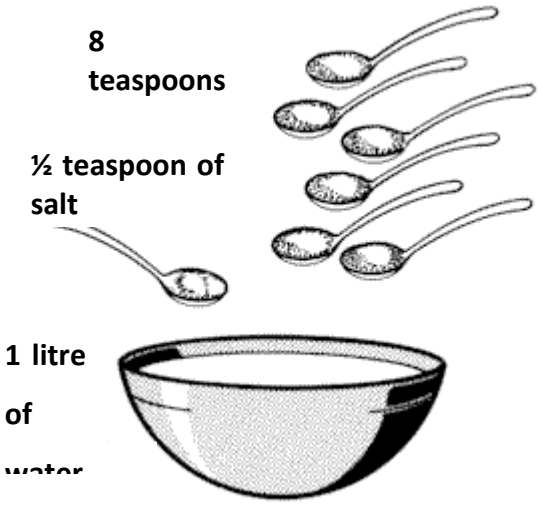
Has the diarrhoea lasted for more than 5 days without improving?

Yes → Go to the clinic

No ↓

Treat your diarrhoea at home

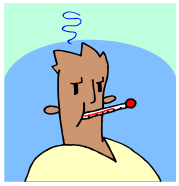
Home treatment for diarrhoea: The most important thing with diarrhoea is to make sure that you are getting enough fluids so that you do not become dehydrated. Try to avoid drinks with caffeine in them as they can cause more dehydration (coca-cola, coffee and tea all have caffeine). Drink your fluids at room temperature, hot drinks or cold drinks can make your diarrhoea worse. Making a ***glucose drink*** is the most effective treatment for diarrhoea. Make this by filling a clean one-litre bottle with clean water from a tap or boiled water if you are not sure that the water is clean. Add 8 teaspoons of sugar and half a teaspoon of salt to the water and mix it well. You can add half a cup of orange juice if you find you don't like the taste. Try to drink one to two cups (200ml) after each loose stool (bout of diarrhoea). Take small sips and drink it slowly.

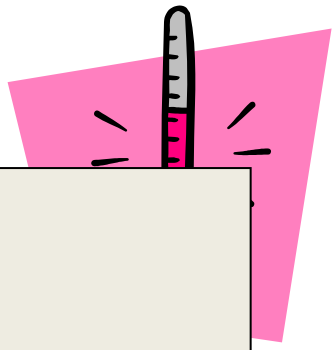


If you have diarrhoea you might not feel like eating but skipping food is not a good idea. Try plain foods like dry toast white rice noodles, mashed potatoes or white bread. Eat any food that doesn't make you feel sick. Make sure you wash your hands before and after handling food. Usually diarrhoea will go away on its own within a week.

Fever

Fevers or having a high temperature are most commonly caused by infection. In people living with HIV/AIDS the fever can be caused by the HIV itself but it can also be caused by other infections or even by medications. If you have a fever you need to check that you do not have any other symptoms of serious illness warning you to take action straight away. Use the fever action chart to check for these.





Fever Action Chart:

Do you have a fever and?

- *Neck stiffness (you can't bend your neck to put your chin on your chest)*
- *Extreme tiredness or feel confused*
- *Fitting or seizures*
- *Severe irritability*

Yes → Go to the clinic now

No ↓

Do you have a fever with a *dry cough and severe shortness of breath*?

Yes → Go to the clinic now

No ↓

Do you have *a new skin rash or skin sores* with this fever?

Yes → Go to the clinic

No ↓

Do you have any of the following with your *fever*?

- *Headache*
- *Sore throat*
- *Cough*
- *Diarrhoea*
- *Urinary problems*

Yes → See the action plan for that problem

No ↓

Treat your fever at home

Home treatment for fever: A high fever can be treated by sponging the body down to cool it down, or by using medicine. Sponging the body down with luke-warm water (not cold water) helps to bring the temperature down. Paracetomol (Panado) can also be used to lower a temperature.

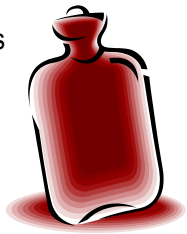
Headaches:

Headaches are one of the most common symptoms experienced by people both with and without HIV/AIDS. Headaches can be caused by muscles becoming tense, they can also be caused by medication. Headaches with fevers can be more serious. If you have a headache with a fever and stiff neck – *a neck so stiff that when you bend it forward you can't put your chin on your chest,* you may have meningitis. This is a serious infection of the lining of the brain which needs to be treated immediately. Use the headache action plan to decide how to manage your headaches.

Headache Action Chart:

Do you have a *fever and neck stiffness* with your headache?	Yes →	Go to the clinic now
No ↓		
Do you have any of these with your headache? • *Difficulty moving your arms or legs* • *Difficulty with seeing* • *Difficulty speaking (slurring)*	Yes →	Go to the clinic now
No ↓		
Has your headache lasted more than 3 days?	Yes →	Go to the clinic
No ↓		
Treat your headache at home and discuss it at the clinic at your next routine appointment		

Home treatment for Headaches: Paracetomol is very effective to treat a simple headache. This medicine works better if you take it as soon as you feel the headache rather than waiting until the pain is so bad you can't take it anymore. If the headache is due to muscle tension and stress then rubbing the neck muscles and putting something warm on the neck (a hot water bottle wrapped in a towel) can help. Relaxation techniques and resting is also very effective to manage headaches.



Eye problems:

People living with HIV/AIDS can get many eye problems. All eye problems should be checked at the clinic. Eye problems can be caused by infection (CMV), but, eye problems can also be caused by medicines, high blood sugar (diabetes), headaches, eye strain and normal changes with ageing. If you develop eye problems *suddenly* then it is likely that this is caused by an infection and you need to go the clinic straight away. If your eye problems have come on slowly then you need to get your eyes checked the next time you go to the clinic.

Eye Problem Action Chart:

Did *blindness* (part or total) come on *suddenly* in one or both eyes or is *the loss of vision severe*?	Yes →	Go to the clinic now
No ↓		
Is your CD4+ count more than 200	Yes →	Go to the clinic
No ↓		
Have you had *gradual loss of vision equally in BOTH* eyes	Yes →	Go to the clinic
No ↓		
Go to the clinic NOW		

Nausea and Vomiting:

Many of the worries about nausea and vomiting are the same as for diarrhoea. Medicines are the most common cause of nausea in people with HIV/AIDS but this can also be caused by viral infections. Dehydration is the biggest risk. Signs of dehydration may be dizziness, severe thirst, dry mouth and tongue, decreased and very dark urine, wrinkled and dry skin. Black or bloody vomit can be a sign that there is bleeding in the stomach.

Nausea and Vomiting Action Chart:

Do you have any of these?

- *Black or bloody vomit*
- *Severe steady stomach pain*
- *Headache with a stiff neck (you can't put your chin on your chest)*

Yes → Go to the clinic now

No ↓

Do you have any signs of dehydration?

- *Extreme thirst*
- *Very dry mouth*
- *Dark urine*
- *Lightheadedness or dizziness*

Yes → Go to the clinic now

No ↓

Has this started after starting *new medicines*?

Yes → Go to the clinic

No ↓

Are you pregnant or do you think you might be *pregnant*?

Yes → Go to the clinic

No ↓

Have you been vomiting for *more than 3 days without improvement*?

Yes → Go to the clinic

No ↓

Treat vomiting at home

Home treatment of Nausea and Vomiting: It is important to get as much fluid into your body as possible without vomiting again. Sipping the glucose drink described for diarrhoea is important. Don't try to drink a whole glass all at once, sip it slowly so that you do not vomit again.

Shortness of Breath:

It is normal to feel short of breath when you do strenuous activity or exercise. If you get short of breath when you are resting or when you do very little activity or if you wake up at night feeling short of breath then you need to go to the clinic urgently. The main cause for this kind of problem in people with HIV/AIDS is PCP. Shortness of breath can also be caused by lung infections you have had in the past and smoking.

Shortness of Breath Action Chart:

Do you have *shortness of breath at rest or with very little activity*?

Yes → Go to the clinic now

No ↓

Do you have a *dry cough* or *fever* with your shortness of breath?

Yes → Go to the clinic now

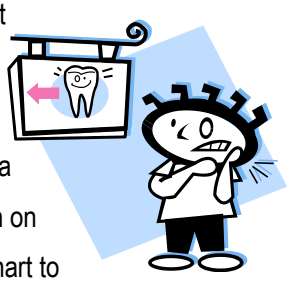
No ↓

Treat at home and go to the clinic

Home treatment for Shortness of Breath: If you are busy with something when you become short of breath you should not stop straight away or try to hurry up to finish. It is best to slow down what you are doing and see if your breathing settles down. Sometimes when we feel short of breath we worry about it which makes us afraid and can make our breathing even worse. If you have not been very active for a while, your shortness of breath might be a sign that you need to get fitter. You need to slowly increase your activity over time as discussed in the section on exercise. If you smoke and you are getting short of breath you need to try to stop smoking. If you are struggling with stopping smoking then speak to the nurse on your next visit to the clinic. If people smoke near you, try to avoid their smoke or ask them to smoke away from you. If you are short of breath it is helpful to practice the deep breathing exercises described in the section on relaxation. This kind of deep breathing helps to train the muscles for breathing and also helps your mind to manage your symptoms.

Sore Throat and mouth:

Sore throats are common in people with and without HIV. The most common causes of a sore throat are the cold viruses but a sore throat can also be caused by other infections. Most sore throats can be treated safely at home. A sore mouth and sore ears are also common. Patches in the mouth, white patches on the tongue or mouth or red burning patches which are itchy and sores in the mouth or down your throat can all be caused by thrush. Pain in the mouth can be caused by teeth with holes. Teeth can get holes because of bacteria in the mouth. You can prevent these by brushing your teeth twice a day and after very meal. It does not take much toothpaste (a drop the size of a pea is enough) to keep your teeth clean. It is also important to cut down on sweets and fizzy drinks which cause teeth to rot. Use the sore throat and mouth action chart to decide on what you need to do.



Sore Throat and Mouth Action Chart:

Do you have severe difficulty breathing or swallowing? — Yes → Go to the clinic now

No ↓

Do you have a fever or pus in the back of your throat? — Yes → Go to the clinic

No ↓

Do you have pain in your teeth or swelling in your cheek? — Yes → Go to the dental clinic

No ↓

Do you have sores or white patches in your mouth, on your tongue or on your lips? — Yes → Go to the clinic

No ↓

Has your sore throat *lasted more than 10 days*? — Yes → Go to the clinic

No ↓

Treat at home

Home treatment for a sore throat and mouth: Drinking cool liquids and taking painkillers like paracetomol can help. You can also treat a sore throat by gargling with salt water. It may also help to suck on ice cubes if you have access to ice.

Skin Problems:

There are many skin problems which can affect people living with HIV/AIDS. Very few of these problems are dangerous but because they can be seen they can be very upsetting. Being able to see these might make you feel unattractive or have low self-confidence, they often last a long time and can constantly remind you of your HIV status. The most common skin problems people with HIV/AIDS have are shingles, chicken pox, bacterial infections, warts, fungal infections and rashes.

Skin Problems Action Chart:

Do you have a rash which is *painful* on one side of your body or on your face?
Yes → Go to the clinic today

No ↓

Has the rash started after starting new medicines?
Yes → Go to the clinic today

No ↓

Do you have a rash or blisters on your body and a *fever*?
Yes → Go to the clinic today

No ↓

Do you have warts on your skin which are a different colour to your skin?
Yes → Go to the clinic

No ↓

Do you have a rash in *a circle* on your skin or *white dying skin* between your toes, in your groin, around your private parts or under your arms or is there *pus in the rash*?
Yes → Go to the clinic

No ↓

Treat at home

Home treatment for skin problems: It is important to keep the skin clean to prevent any infections developing. Wash your whole body with soap and water every day. Keep your fingernails short and clean. If you are scratching in your sleep, you can sleep with socks over your hands so that you do not damage your skin. If your skin is dry and itchy, it helps to wash with aqueous cream instead of soap.

Urination problems:

Urinary infections happen more often in women than in men, but men with HIV/AIDS are more likely to get these infections too. The most common symptom of a urinary infection is pain or burning when you pass water, frequent need to pass water and blood in the urine. These symptoms are not always caused by an infection; they can also be caused by too much caffeine (tea, coffee, cola); bladder spasms (when the bladder becomes overactive) and even anxiety. Bladder infection in women can also be caused by sexual activity. If you also have a fever, vomiting, back pain or teeth-chattering or body-shaking chills it is likely that the infection has spread from the bladder to the kidneys. Use the Urination Problems Action Chart to help you decide how to manage your symptoms.

Urination Problems Action Chart:

Do you have a *fever, vomiting, back pain, shaking chills* as well as *painful or frequent or bloody urination*?

Yes → Go to the clinic today

No ↓

Could you be pregnant?

Yes → Go to the clinic today

No ↓

Do you also have a *new irritating vaginal discharge*?

Yes → Go to the clinic today

No ↓

Do you have pain in your stomach (abdomen) as well as a vaginal discharge?

Yes → Go to the clinic today

No ↓

Treat at home and go to the clinic if it does not clear up in 2 days.

Home treatment of urination problems: The first step in managing these problems is to drink a lot of water. Drink several litres (4 to 5 litres) of water in the first 24hours after these symptoms start. This helps to wash out anything which might be causing the problem. Drinking fruit juices can also help as these change the chemical content of the urine. If you have a new vaginal discharge or pain in the abdomen it is important to go to the clinic as this means that the symptoms may not be coming from the bladder but from the vagina which needs medical treatment.

A final word on symptoms:

Remember the steps described in this section and the action charts do not replace nurses and doctors. The information in this section is to help you work ***with*** your health team. Use the action charts to help with thinking about any symptoms you experience and to help you decide what you need to do about them. As you have read, some symptoms it is perfectly safe for you to manage at home. Some symptoms you need to go to the clinic straight away for. If you have any doubt or any worries about any of the symptoms you experience then it is best to go to the clinic to get them fully assessed. Remember what you learnt in the first section on how to be a good self-manager. Use the information in that section to help you get the most out of any visit to the clinic about any symptoms you experience.

When you do visit the clinic for a symptom you may be treated by the nurse or doctor. Or may be referred to someone who specialises in the problem you are experiencing. In the next section, we will discuss how to communicate well with your health carer. No matter who you are seeing at the clinic, it is useful to use the steps on communication to get the most out of your clinic visit.

Use the "Action Plan Form" at the end of this section to plan how you will manage a symptom which you experience. Use the "Exercise Diary" to keep track of the exercise plan you started last week. Remember these charts are designed to help you become a successful self-manager!

Action Plan Form – Managing Symptoms

Think about a common symptom which you experience. Use this form to draw up an action plan of how you plan to manage this symptom the next time it occurs.

Be sure your action plan includes:

What you want to do

How much you are going to do

When you are going to do it

How many days a week you are going to do it

For example: This week, I will walk (*what*) around the block (*how much*) before lunch (*when*) three times (*how many*).

This week I will:

_____ *(what)*

_____ *(how much)*

_____ *(when)*

_____ *(how many?)*

How confident are you that you can complete this action plan?

Not at all | | | | | | | | | | Totally confident

1 2 3 4 5 6 7 8 9 10

Keep a record of how you did, when I feel sick:

	I Plan to…..	**I did…..**
Monday		
Tuesday		
Wednesday		
Thursday		
Friday		
Saturday		
Sunday		

Exercise Diary

Use this exercise diary to keep track of the exercise goals and plan you drew up in week one.

Start off by writing down your goal.

Write down here what you want to be able to do: _____

Now, what do you want to be able to do *this week* which will help you to reach your goal?

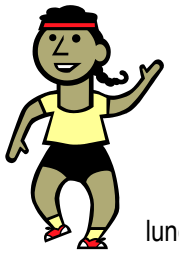
Remember from your action plan to include:

What you want to do

How much you are going to do

When you are going to do it

How many days a week you are going to do it



For example: This week, I will walk (*what*) around the block (*how much*) before lunch (*when*) three times (*how many*).

This week I will:

_____ *(what)*

_____ *(how much)*

_____ *(when)*

_____ *(how many?)*

	Exercise Planned	**Exercise I did...**	**How did I feel? Do you need to change anything?**
e.g.	*20 mins in a.m. after breakfast and in p.m. after supper*		*Very tired by the second session, I'm going to cut it down to morning only for this week.*
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			

Week 3: Stress Management

In our society, we talk about stress a lot. We might say that it is stressful to live in South Africa. That it is stressful to worry about our children or our families, it is stressful to worry about money or it is stressful worrying about getting a job or coping with my job. We use the word stress a lot, but what does it mean? Stress is a feeling; it is a combination of feeling tense and worried. When we feel stressed we may be irritable, and find it difficult to concentrate or remember things, stress can affect our sleep, our appetite and our relationships.

The most common reason why we feel stressed is a lack of control. We tend to feel that things are stressful if we don't have any control over them. We feel stressed if we are going to be late for work because the trains are late

– this is out of our control. We feel stressed about where we live if we don't feel safe there – those who commit crimes against us are also out of our control. In the same way, we may feel stressed when we have a chronic illness like HIV/AIDS or diabetes or high blood pressure. If you feel that your illness is out of your control and there is nothing you can do to affect it, this makes you feel stressed.

Stress is not always bad. We know that stress can be useful too. For many people if we feel some stress, we might feel under pressure to perform better. You might feel stressed because your family is coming to visit, but this stress makes you tidy up your home – a good effect of the stress. Students who are studying will only complete their studies if there are exams and deadlines for assignments, without the stress of the deadline, the students would not complete the work.

Sometimes we wish for a "stress-free" life. But, we know that if there was no stress in our lives, if we did not have to do anything all day long, this would not be good for us either. If I lay in bed all day and did not do anything, my muscles would get weak, my joints would get stiff and I would become ill. We need some stress in our lives to keep us healthy. The important thing is to keep the amount of stress at a level that we feel we can manage. This is why we talk about stress management, *not* stress elimination!

There are many different things we can do in our lives to manage stress. The first step is to understand why we are feeling stressed. There are usually three things which affect how stressed we feel.

1. The stressful situation:

Usually the less you expect the situation and the less familiar you are with a situation, the more stressful it will be. If you needed to take the taxi to work but you knew the day before that the taxi would come late, this would be less stressful than finding out while you are waiting for the taxi that it would make you late. If you think about having pain, if you know the cause of the pain is it more or less stressful? If you don't know what is causing your pain and you are worrying that there is something seriously wrong, is this more or less stressful?

2. How you see the situation and how you cope with it:

If the situation you are in is not important, you are likely to feel less stressed about it. If you are in a taxi which is going to be late, but you are going shopping on your own, then you are likely not to get so stressed about it. If you are in a taxi which is going to be late and you are going to work this might be more stressful, but if you have a cell phone with you and you have airtime on the cell phone and you telephone your boss to explain why you will be late, then this might be less stressful. Your ability to cope with the situation, affects the amount of stress you feel. While it is stressful to live with a chronic disease like HIV/AIDS, diabetes or high blood pressure, if you thought you could cope with it and it would not interfere with your job and your life would it be more or less stressful? Having knowledge about your condition allows you to think about it in a different way and will change the way that you cope.

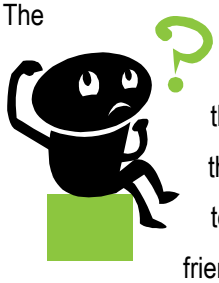
3. Support from family and friends:

Friends and family who understand and support you will affect your levels of stress. Feeling alone and like you have no support will probably make you feel more stressed. If you think about living with HIV/AIDS, would it be more or less stressful if there were no one to support you? But, we do need to be careful about support from family and friends. If they take over doing everything for us (because they care about us and are trying to help), we might feel useless and like we don't have a purpose. Support does not mean doing everything for me.

Stress is not just the things that happen to us. The amount of stress that we feel depends on a lot of different things which can change every day. There are many different things we can do to manage stress every day. **You can ask for assistance at a clinic or you could discuss what options there are at the Jabulani ARV clinic or with your doctor. If you can afford to get transport you can go to an NGO like FAMSA who specialise in family and relationship counselling.**

Managing Stress:

1. Dealing with the cause of the stress



The first step in dealing with stress is to identify *why* you are feeling this way. Use the self-management steps to help you identify the problem. Once you know why you are feeling this way then you need to decide what you can do about it. Sometimes dealing with the things that stress us is easy, if you are friends with your neighbours and the noise from their television is irritating you it might be easy to ask them to turn down the volume. If you are not friends with your neighbours, or you are very shy it might be quite difficult to ask them to turn down the volume. Sometimes we can identify the things that stress us and do something about it. But, often we either cannot deal with it or it is out of our control. If you cannot deal with it or it is out of your control, the next step is to change the way you are looking at the problem.

The second step is to look at the problem in a different way. Think about how you are feeling. Are your thoughts and feelings about the problem inaccurate? Maybe you are very worried about your health, this is stressing you. Are you worried that you will be very ill and unable to work soon? Are these thoughts and feelings accurate? On what information are you basing these thoughts and feelings? Have you spoken to experts about your health or are you basing your thoughts and feelings and stress on poor information?

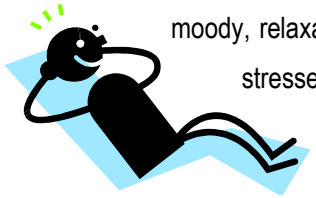
Step three is - plan your life. Do you get stressed by the same things over and over again? Or do you find yourself getting stressed because there are times when your life is very busy? If you are doing the same things over and over and getting stressed, you might want to look at how you are dealing with it and see if you can try a different plan. What about a busy life? This is also about planning, being very busy and having no time for ourselves, can be very stressful. Plan things over time carefully, make sure you have time to at least do some relaxation or exercise even when you are very busy. Do not leave things for the last minute.

The last step to deal with stress is to get help. Family and friends and support groups are a great way to decrease stress. If we want support from people though, we have to tell them clearly what the problem is and what we would like from them. Often we do not communicate clearly and this might make the stress worse! If you find your family or friends are not very helpful or supportive, it might be worth sitting down with them when you are not feeling stressed to talk about these things. It might be that they see things differently to you, this does not mean they are right and you are wrong, or that you are right and they are wrong. It just means that you see things differently and you can discuss how to handle things better. If having a discussion like this is difficult, it might be useful to ask a counsellor to help with the conversation. You can ask for assistance at a clinic or you can go to an NGO like FAMSA who specialise in family and relationship counselling.

2. Relaxation

When we feel relaxed, we feel calm. Sometimes if we are relaxed and we are tired, we might feel sleepy. At other times we might feel relaxed and alert and be able to concentrate calmly on tasks. Relaxation can help us to concentrate and it can help us to unwind and go to sleep. Relaxation is a very useful way to manage stress and some of the symptoms of chronic diseases such as pain.

If we are stressed, this can make our muscles tense, our hearts beat faster and we breath faster, if we are also feeling unwell and have pain we will feel worse. Relaxation can decrease the tension in muscles and slow down our hearts and breathing and help to make us feel better. If we are stressed we often become irritable and moody, relaxation helps to calm you and make you feel more in control of your life. When we are stressed sometimes it is difficult to fall asleep as we are worrying about things out of our control, if you are also unwell, not sleeping will make you feel worse. Relaxation will help you get to sleep, this will help manage your stress and improve your health.



Just like learning to play a new sport or doing exercise, relaxation takes practice. The specific way that you relax doesn't matter; we are all different and might relax in different ways. The important thing is to practice it regularly. There are two different ways of relaxing described at the end of this section. You can do these at home in a quiet and comfortable safe place to begin with. But, once you get good at relaxation, you can relax in a crowded waiting room, on a train or a taxi. You can do relaxation anywhere!

Good times to practice relaxing are when:

- You feel you are getting tense or irritable or you are worried
- You feel you are in pain
- You want to go to sleep

3. Sleep

People with chronic illnesses often struggle to sleep because they are stressed and worried about their condition, they worry about what this means for them, for their family, for their future. People also often struggle to sleep because of the illness itself, perhaps you have pain, you feel sick or you may even be so tired you can't sleep. Some people find it difficult to get to sleep and only fall asleep very late at night, others find that they fall asleep but then wake up during the night and can't get back to sleep. Some people find it difficult to sleep at all at night and sleep during the day.

Sleep is very important to keep healthy. We all need different amounts of sleep. Some people need 8 hours of sleep a night, some may need 10 hours and some people only need 5 hours of sleep. We are all different. We have been learning how to fall asleep and sleep well since we were babies. If you do not sleep well, following these steps will help you to learn how to fall asleep and sleep well. Remember that like learning anything new, this will take time. It might take up to 3 months to learn to sleep well if you have been struggling with sleep for a while.

Suggestions for Improving Sleep

1. *Have a bedtime routine*: try to go to bed at around the same time every night and always do the same things before getting into bed. A bedtime routine could be to lock the house, get undressed, wash your face, clean your teeth, get into bed and do a relaxation session.

2. *You can't sleep because of worrying*: write down your problems or the things that are worrying you, then write down the next step that you think could help sort out the problem. If you wake up during the night worrying about the problem, remind yourself that you've gone over it and you have a plan. If you wake up with a new worry, write down that problem to deal with in the morning. Practice your relaxation to take your mind off the worry. If you still can't sleep, it may be better to get up and do something relaxing like reading, watching TV, listening to relaxing music or doing relaxation.

3. *Your bed and bedroom are for sleeping*: try not to use your bedroom during the day. Do not watch TV in bed. If you are not asleep within 30 minutes of going to bed, get up and do something else. Do not lie in bed and worry that you have not fallen asleep. This will only make you feel stressed and lessen the chance of falling asleep.

4. *Have a morning routine*: get up at the same time every day, even if you don't feel like it. Our bodies like to work on regular patterns to fall asleep and get up at the same time every day.
5. *Avoid drinks containing caffeine* for at least 4 hours before going to sleep (drinks like coke, tea or coffee).
6. *Never use alcohol to help you sleep*. It might make you feel relaxed at first, but once this wears off it is likely to make you feel jumpy and you are likely to wake up during the night.

Good sleep habits:

- Go to sleep at the same time every day
- Have a bedtime routine
- Do relaxation before going to sleep
- Use your bed only for sleeping or relaxing
- Have a morning routine

4. Exercise

Exercise is a very effective way of managing stress. People who exercise regularly doing at least 20 to 30 minutes of exercise, 3 times a week have less risk of suffering from stress related illnesses. Go back to the section on exercise for more on how to exercise safely and effectively.

Exercise:

- Decreases stress
- Helps us sleep better
- Decreases pain
- Makes us healthy and decreases our chances of developing other illnesses

5. Communicating with your health carer

Anyone living with a long term health problem, whether it is HIV or high blood pressure or diabetes will have to visit their clinic regularly. Visiting the clinic regularly can be stressful because it takes time, you have to plan ahead, you might not be sure how long you are going to have to wait, you might be worrying about what the health carers are going to tell you. One of the most important ways of managing the stress associated with visiting clinics and seeing health carers is to think about and plan how to communicate with them.

When visiting the clinic to see a health care practitioner it is important that you feel comfortable asking questions (any questions, even if you feel they are "silly" or "stupid" questions) and comfortable expressing how you feel. It is also important that you feel you can negotiate your treatment with your health care provider so that both you and the carer feel that you are receiving the best care for you. It is important that you not feel that your health care provider is ignoring you, "puts you down" or treats you like a child. We know that doctors and nurses have a lot of patients to see and they have little time to spend with each person. One helpful way to make sure that you get the most out of your appointments with the doctor or nurse is for you to take PART – Prepare, Ask, Repeat, Take action.

Take PART:

Prepare:

Before your appointment at a clinic it is important to prepare. Think about the reason for your appointment and whether there are any issues in particular that are worrying you. Write down your questions or the things that are worrying you. You need to be realistic about the list you write down, there will probably only be time to answer one or two of the things on your list. Make sure the most important problems are at the top of the list. Take your list with you to your clinic appointment, then when the doctor or nurse asks if there is anything you want to ask, you can use your list.

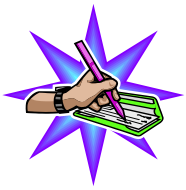
If there are particular symptoms or health issues you want to discuss, prepare for your appointment by writing down specific information the doctor or nurse will want to know. Things that are helpful are: when did it start, how long do the symptoms last, where are they in your body, what makes you feel better or worse, have you had a problem like this before and how was it treated; have you changed anything such as your diet, exercise, medicines. If you have already received treatment for a problem, be ready to report back on how well it has worked, or on whether it has not worked at all.

Be open about how you are feeling and about the things that are worrying you. The more open you are, the more the health care provider can help you. Finally, give feedback. If you don't like the way you have been treated you can tell the doctor or nurse. If you do not want to tell them directly then you can speak to someone else in the clinic or to someone in a support group. Remember too that doctors and nurses and other health care providers also appreciate being complimented. If you feel that you have been treated well and are happy with your treatment, it is acceptable to compliment the health carer.

Ask:

Another important step in having good communication and decreasing stress is to ask questions. Having good information is essential to you being successful in self-managing your health. Ask questions about your diagnosis such as what is wrong, what has caused it, is it contagious and what is going to happen now? Then ask questions if you have had tests, what is the test for; what if I don't have the test and what will the test involve? Remember to ask questions about your treatment options, what are the benefits of treatment and what are the risks and side effects? Finally ask questions about follow-up, when should you return to the clinic, what should you watch out for and what should you do next?

If you find you have difficulty remembering information it is a good idea to write things down during your visit. Or you could ask someone you trust to come to the appointment with you to help with remembering.



Repeat:

One of the important things to do to help with remembering things is to repeat it. So if the nurse or doctor explains something to you, repeat back to them in your own words what you have understood. This is very useful to make sure there are no misunderstandings.

Take Action:

At the end of your appointment, it is important that you know exactly what you will need to do next. It might be that you need to make another appointment, or that you need to go home and change something or get new medicine from the pharmacy. Make sure that you are clear about what you need to do next, and then do it!

Relaxation

Long relaxation:

Find a comfortable position. Lie on your back or sit in a chair with your back supported.

Place your hands at your sides, palms up.

Close your eyes if you wish.

Now begin to become aware of your breathing..... Focus on slowing down the rhythm of your breathing.....

Your chest and tummy will expand outward with each breath, like a balloon gently filling with air....

Imagine your ribcage moving out to the sides when you breathe in.... and gently inward as you breathe out....

Slowly take a deep breath in.... Pause for a moment.... and then slowly breathe out. Let the tension melt away as you relax more deeply with each breath...

Continue breathing slowly and gently....

Now think about the top of your head. Feel the skin on the top of your head beginning to relax, and spreading slowly downwards....

Even your ears are becoming relaxed and heavy.... Feel your eyebrows resting....

Your forehead is becoming relaxed and smooth....all the lines on your face are becoming smooth..

Let your jaw relax by allowing your mouth to be slightly open.... Allow your tongue to relax...

Feel your throat relaxing.... relax your cheeks, nose, and eyes.... Feel your eyelids becoming very heavy.... and very relaxed.... more and more relaxed....

Enjoy the feeling of relaxation you are experiencing.

Now think about your neck.... allow a feeling of relaxation to begin at the top of your neck, and flow downward...

Feel the relaxation as your shoulders become relaxed and loose.... Let your shoulders gently sink downward.... as they become relaxed.... and heavy.... very heavy.... and very relaxed.... deeper and deeper.... relaxed....

Feel your collar bones becoming relaxed as your shoulders move gently back, and your chest widens slightly....

Allow all the muscles in your shoulders to feel smooth... and relaxed.... as the muscles give up their hold completely...

Notice your breathing once again... see how regular it has become... continue to take slow.... smooth.... deep breaths... Breathe in the feeling of relaxation... and breathe out any tension... your breathing allows you to become more and more relaxed.... deeply relaxed..... Now turn your attention to your right arm..... Feel the relaxation flowing down from your right shoulder.... allow your upper arm to relax... your elbow.... lower arm... and wrist become loose and relaxed....

Enjoy the feeling of relaxation as the muscles of your right arm give up their hold.... Feel the relaxation flowing into your hand... Let all the tension drain out of each finger tip and flow away.... the relaxation spreads to your thumb... index finger.... middle finger... ring finger... and little finger....

Feel the relaxation flowing down your left arm... Let the muscles of the left upper arm relax.... Relax your elbow.... lower arm.... and wrist....

Enjoy the feeling of relaxation you are experiencing.

Let the tension melt away.... imagine the tension flowing right out of your finger tips... Allow your left hand to relax completely.... relax your thumb... index finger.... middle finger... ring finger... and little finger....

Both of your arms are now totally relaxed... allow them to be free and limp... pleasantly relaxed...

Enjoy the feeling of relaxation you are experiencing...

Allow the feeling of relaxation to continue to your chest and stomach....feel the relaxation there... becoming deeper with each breath....

Now turn your attention to your upper back... Feel the relaxation flow down your spine... Let all the muscles give up their hold.... relax your upper back... middle and lower back.... allow your back to relax completely..... Feel the relaxation in your whole upper body ....

Relax more deeply with each breath.... more and more relaxed.... deeply relaxed and calm....

Let your hip muscles relax.... Relax all the way from your buttocks (bottom), down the back of your thighs... relax the muscles on the front of your thighs...Feel the relaxation in your upper legs moving down to your knees... your calves and shins.... your ankles.... and your feet.... allow all the muscles to relax and go limp....

Allow any last bits of tension to flow right out of the soles of your feet....Feel the relaxation flowing through your body... From the top of your head... down to the bottoms of your feet.... become more relaxed with each breath.... enjoy the feeling of total relaxation.....

You are now as relaxed as you want to be.... Experience the feeling of deep relaxation... enjoy the feeling.... relaxed.... calm..... at peace

Focus on the feeling of relaxation throughout your body.... Notice your breathing.... Your relaxed muscles.... Your calm thoughts... Memorize this feeling so you can re-create this relaxed state whenever you wish....

Enjoy relaxing for a few moments more....

When you are ready to return to your day, reawaken your body slowly... gently move your muscles... roll your shoulders slowly forward.... then slowly backward.... lean your head gently to the left... return to centre.... lean your head gently to the right... turn your head...

Wriggle your fingers and toes....

Gently open your eyes.... Feeling alert... calm.... and full of energy.

Short relaxation:

Deep breathing not only helps to cure anxiety and stress, it also triggers relaxation. Here's how to breathe deeply.

Breathe in slowly to the count of four (count slowly; to the pace of one-one-thousand, two-one-thousand....).
Pause to the count of three.
Breathe out slowly to the count of five.
The breathing process goes like this:
Inhale... two, three, four...pause...two, three....exhale...two, three, four five....
Inhale... two, three, four...pause...two, three....exhale...two, three, four five....
Repeat for a minute or two.

Action Plan Form – Stress Management

Think about one thing that is causing you stress. Use this action plan form to come up with a plan of how to manage your stress this week.

Be sure your action plan includes:

What you want to do

How much you are going to do

When you are going to do it

How many days a week you are going to do it

For example: This week, I will walk (*what*) around the block (*how much*) before lunch (*when*) three times (*how many*).

This week I will:

_____*(what)*

_____*(how much)*

_____*(when)*

_____*(how many?)*

How confident are you that you can complete this action plan?

Not at all confident	| 1	| 2	| 3	| 4	| 5	| 6	| 7	| 8	| 9	| 10	Totally confident

Keep a record of how you did:

	I Plan to…..	**I did…..**
Monday		
Tuesday		
Wednesday		
Thursday		
Friday		
Saturday		
Sunday		

Exercise Diary

Use this exercise diary to keep track of your exercise goals and activities.

Start off by writing down your goal.

Write down here what you want to be able to do: _____

Now, what do you want to be able to do *this week* which will help you to reach your goal?

Remember from your action plan to include:

What you want to do

How much you are going to do

When you are going to do it

How many days a week you are going to do it

For example: This week, I will walk (*what*) around the block (*how much*) before lunch (*when*) three times (*how many*).

This week I will:

_____ *(what)*

_____ *(how much)*

_____ *(when)*

_____ *(how many?)*

	Exercise Planned	**Exercise I did...**	**How did I feel? Do you need to change anything?**
e.g.	*20 mins in a.m. after breakfast and in p.m. after supper*		*Very tired by the second session, I'm going to cut it down to morning only for this week.*
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			

Week 4: Pain

Many people living with HIV/AIDS experience pain and it is very often the symptom which bothers them most.

We know this from lots of scientific studies conducted across South Africa, Africa and the rest of the world. There can be many reasons for someone living with HIV/AIDS to have pain. The pain may be caused by the virus, or the pain may be caused by the medicines used to keep you healthy or the pain might be for a reason that has nothing to do with HIV/AIDS.

The pain may be caused by the disease, for example if the virus damages nerves you may feel pain. Pain may also be caused or made worse by tense muscles. When something hurts we tend to make our muscles tense to try and protect ourselves. Pain may also be caused by weak muscles or stiff joints. People with HIV/AIDS often become less active and their muscles and joints get weak and stiff. Then when they do use their muscles and joints these can hurt because they haven't been used for a long time and they aren't used to it. Finally stress, fear, anxiety and depression can cause pain and make pain worse. We know from research that when you are in pain your brain is very active. If you are also stressed, or afraid, worried or anxious, or depressed, your brain becomes even more active. This does not mean that your pain is not real, what it does mean is that activity in your brain can cause pain or if you are already in pain, it can make it worse.

To properly treat pain we have to make sure that we check and treat all the possible causes of pain.

Checking the cause of pain

If you develop a new pain which you have not felt before it is important for you to pay attention to it. Pain is your body's way of getting your attention that something might be wrong. It does not always mean that something is wrong; it may just be a warning. It's like when you put your hand on something hot, it hurts and you pull your hand away. Often your hand is not burnt, but it was painful, the pain got your attention quickly and you moved your hand before you got burnt.

If you have not felt the pain before it is important for a doctor or a nurse to examine you to find the cause of the pain. If they find the cause of the pain they may give you medication to treat the cause. If you have TB you might have pain, the doctors or nurses might give you medicine for the TB to treat the cause of the pain. They should also give you medicine for the pain itself. If they forget to give you pain medicine you must ask for it. Sometimes you may only be given pain tablets for a few days, if you know your pain lasts for the whole month you must tell the nurse or doctor this and they should give you medicine for the whole month.

In up to one third of people with HIV/AIDS who have pain, the doctors or nurses might not find any reason or cause for the pain. This does not mean that the pain is not real or that it should not be treated. If they do not find a clear cause for your pain they should still give you pain medicine.

What can you do for pain?

There are lots of things you can do for yourself to help manage your pain. Because we know that the brain is very involved when someone is in pain, we also know that understanding your illness, being a self-manager who understands about their treatment and, having support can help manage your pain. We are now going to talk about different things that you can do to help decrease pain.

Exercise

Doing any kind of exercise, stretching, strengthening or endurance exercise can all help to decrease pain. We also know that people who exercise regularly have less pain.

Relaxation

Managing stress and doing relaxation exercises also helps to decrease pain. This works because it decreases the activity in the brain. We also know that if you do regular relaxation it can help you to sleep better. People with pain often find that the pain is worse at night and that it is difficult to sleep. Bad sleep can also make pain worse. Doing relaxation and being able to sleep better will help to reduce the pain and help to prevent it getting worse. You can also help your pain by managing stress and anxiety. You can do this by talking to people and getting support, either from a nurse, a counsellor or a support group.

Heat

If your pain is being caused by tense muscles then heat can help to decrease it. You can warm up the muscles by having a warm bath or shower with the water on the affected area. If you cannot have a hot bath or shower, then keeping the muscles warm with clothes or a blanket can also help. There is one time when you should not use heat for pain. If you touch the painful area and it is already hot, this means it is inflamed and you should not make it hotter. If the area is infected or the skin is damaged then it is also better not to make it hot. In both these situations, it is better to use cold.

Cold

Cold is a very good way to treat pain. When we make nerves that send messages warning us about damage cold, they slow down and send fewer messages. This means that we feel less pain. If you have a freezer then you could use a packet of ice or of frozen vegetables on the painful area. Only leave it on your skin for 10 minutes at a time. If you do not have a freezer then putting a damp cloth on your skin (if you have a fridge then use water from the fridge) will also work well.

Massage

Self-massage is a very simple but very good way to treat pain. You may have even been doing it without realising this is what you were doing. If you have ever rubbed a painful arm or leg then you have done some self-massage. You can use a simple cream or baby powder to do massage. Gentle rubbing of a painful area can relieve pain a lot. BUT, as with heat, if the painful area is hot or infected then it is better not to rub it. Rather use cold. If you have pain *and* the painful area is hot, red and swollen this may be a sign of an infection. If you have been using ice on this for a day and it is not getting better, visit the clinic.

Support

As we said before, when we feel pain, our brains become very busy. We often worry about the pain, we may feel scared about what is causing the pain or what the pain means (we often talk about this as stress – "I feel so stressed!"). We might wonder what we have done to be getting pain. The fear and worry we feel when we have pain can make the pain worse. This is why support is so important to help pain. It is helpful to talk to people that we trust about how we feel. It is also helpful to be reassured by a nurse or doctor about what is causing our pain. It may be that worrying about HIV is making your muscles tense and this is causing your neck to pain or causing headaches. It helps if the doctor or nurse can reassure you that the pain is caused by stress. This does not mean that you are making it up or that it is not real! It means that there is something you can do to help the pain. Talking to people, doing exercise and relaxation all help to manage stress and this will help the pain.

Medicine

If you have medicine to help your pain it is important that you take it regularly. Do not wait for the pain to start before you take the medicine, if you wait it will not work as well. If the doctor or nurse has told you to take the medicine several times a day then it is important that you do this, even if you are not feeling any pain at the time; not feeling pain means that the medicine is working. Do not wait for the pain to come back again before taking another pill, it won't work as well.

If your medicines are not helping the pain then you must go back to the nurse or doctor. You might need stronger medicine or you might need to take two different kinds of medicine at the same time.

Common medicines used to treat pain are:

- Paracetomol (panado, dolorol, painamol, painstop) is a very good, very effective and safe medicine for pain. It is important not to take more than 10 tablets per day.
- Aspirin (disprin) is also very good but some people need to be careful with this medicine. If you use it for a long time you need to be careful of side-effects like ulcers, asthma or kidney problems.
- Anti-inflammatories like indomethacin (indocid), dicolfenac (voltaren or panamor) or ibuprofen (brufen or inza) are good if your pain is being caused by inflamed muscles or joints. These must be taken with food. These can also cause side-effects like ulcers.
- Paracetomol and Codeine is stronger than paracetomol on its own. If you have been using paracetomol on its own and taking it as the nurse or doctor told you but your pain is not getting better they may give you paracetomol with codeine.
- Dextropropxyphene (Doloxene) is a stronger pain medicine. This medicine is not easily available at clinics and the doctor or nurse would need to arrange for you to get it.
- Codeine phosphate is much stronger and can only be prescribed by a doctor. This medicine can make you sleepy and can cause constipation.
- Morphine is the strongest pain medicine. It can be taken up to 5 times a day. It also has to be prescribed by a doctor. If you are prescribed morphine make sure the doctor also gives you a laxative to prevent constipation.

Remember that the most important thing about the pain medicines is to take them before the pain starts or as soon as the pain starts. Don't wait for the pain to become severe before you take the pain medicine. It won't work nearly as well.

Pain

- Pain is one of the most common symptoms people living with HIV/AIDS experience
- Pain can be caused by the virus, by tense muscles, by weak muscles and stiff joints.
- Pain can be caused by and made worse by stress and worry
- Exercise, relaxation, cold, heat and massage are all good ways of treating pain
- Medication for pain works best if it is taken regularly and before the pain becomes very bad.

Action Plan Form - Pain

Think about one pain which you commonly experience. Use this action plan form to develop a plan of how you are going to manage that pain.

Be sure your action plan includes:

What you want to do

How much you are going to do

When you are going to do it

How many days a week you are going to do it

For example: This week, I will walk (*what*) around the block (*how much*) before lunch (*when*) three times (*how many*).

This week I will:

_____*(what)*

_____*(how much)*

_____*(when)*

_____*(how many?)*

How confident are you that you can complete this action plan?

Not at all confident	| 1	| 2	| 3	| 4	| 5	| 6	| 7	| 8	| 9	| 10	Totally confident

Keep a record of how you did:

	When I have pain I plan to…..	**I did…..**
Monday		
Tuesday		
Wednesday		
Thursday		
Friday		
Saturday		
Sunday		

Exercise Diary

Use this exercise diary to keep track of your progress with your exercise goal which you set in week one.

Start off by writing down your goal.

Write down here what you want to be able to do: _____

Now, what do you want to be able to do *this week* which will help you to reach your goal?

Remember from your action plan to include:

What you want to do

How much you are going to do

When you are going to do it

How many days a week you are going to do it

For example: This week, I will walk (*what*) around the block (*how much*) before lunch (*when*) three times (*how many*).

This week I will:

_____ *(what)*

_____ *(how much)*

_____ *(when)*

_____ *(how many?)*

	Exercise Planned	**Exercise I did...**	**How did I feel? Do you need to change anything?**
e.g.	*20 mins in a.m. after breakfast and in p.m. after supper*		*Very tired by the second session, I'm going to cut it down to morning only for this week.*
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			

Week 5: Eating Well

Eating well is important for everyone, eating well helps keep you healthy and if you are sick, either with HIV or any other illness, eating well is important to help you feel better. Treatment is not just taking anti-retroviral medicines; it is taking anti-retroviral medicines and eating well. When you are living with HIV, your body burns more energy than someone who does not have the virus. The virus makes your body use 10% more energy even when you are feeling well and between 20% and 30% more energy when you are feeling sick. This means that you have to eat more just to keep your weight the same. Losing weight is one of the most common symptoms of HIV. People with HIV mostly lose muscle weight, which makes them thin and also makes them weaker. So, how do you stop losing weight, or if you have already lost weight, how do you help your body recover? It is not difficult or complicated to eat well to stay healthy. We are going to discuss some simple steps to follow to eat well.

What should I eat?

Our bodies need energy to be able to do all the things we need to do every day. This energy comes from food and the best source of energy is food which has complex sugars in it. Complex sugars are not sweet, they are foods that many of us eat every day – the starch foods. Starchy foods like bread, pap, rice, potato and mngqusho are high energy foods (complex sugars). When our bodies run out of this high energy food, it will start to use energy stored in the body. Before you had HIV, your body would use fat to provide energy. But, now with the virus your body uses energy stored in muscles – protein energy. If you do not eat enough, your body will run out of complex sugars to give it energy and will start using protein from the muscles. This means that you will start to lose muscle and not fat – we call this wasting. If you eat foods with complex sugars (starchy foods - energy foods) regularly you can stop this happening. If you have already lost weight because of the virus, then you need to eat food with protein to help your muscles recover. Try to make sure you have high energy food (starchy food) with every meal.

One of the important steps for eating well is to eat small meals or snacks often through the day. It is best to try and eat 3 meals a day and have another 2 snacks a day. This means that we should eat 5 times a day; these meals do not all need to be big meals, a snack might be some fruit, nuts or sour milk. By eating 5 times a day we can make sure that we do not run out of energy. When we run out of energy, our bodies have to work harder, if we have pain the pain will get worse, if we are tired we will become more tired, if we are feeling sad we will feel sadder when we run out of energy and if are you are trying to concentrate then it is harder to concentrate when you run out of energy. Also, if you have HIV and you run out of energy your body starts to use the protein in

muscle and you start to develop wasting. For these reasons it is important to eat at least 3 times a day and better to eat 5 times a day.

There is no single food which is good or bad. It is important to eat a variety of foods. We will now talk about the different food groups which we should be eating from every day.

Starchy Foods (also called carbohydrates or complex sugars)

Bread-Potatoes-Pasta-Rice-Sweet Potatoes -Samp-Mealies-Sorghum-Pap-Porridge-Cereals

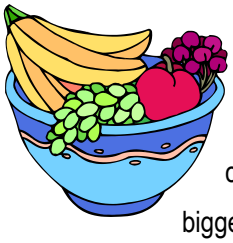
We need to have enough energy, so the starchy foods (complex sugars) should be the main part of our diets. Starchy foods should make up the main portion of all meals. Starchy foods can give us energy for a long time. In the shops or in magazines you might see food labelled "low GI". "Low GI" foods are starchy foods which give us energy for a very long time compared to other starchy foods which are "high GI" which don't give energy for as long. Both these kinds of starchy food are important for people living with HIV.

Fruits and Vegetables

Spinach-Morogo-Pumpkin-Green Peppers-Lettuce-Beans-Squash-Carrots-Tomatoes

Peaches-Apricots-Oranges-Naartjies-Avocados-Paw Paw-Mango-Guavas-Watermelon

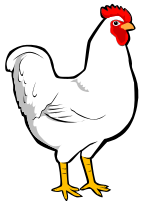
The second most important groups of food which we need are the fruits and vegetables. We should eat at least one fruit and one vegetable with every meal and aim to have at least 7 portions of fruits and vegetables every day. Fruits and vegetables supply vitamins and substances which are important for keeping the immune system strong. Try to eat a variety of fruits and vegetables and include vegetables which are yellow, orange, red or dark green in colour.



These fruits and vegetables contain a vitamin (vitamin A) which helps the lining of the stomach. Citrus fruits like oranges, lemons, grapefruit and naartjies are also important as they contain another vitamin (vitamin C) which helps the immune system to work. You can see in the picture below that the starchy foods and fruits and vegetables are the biggest sections of food.

Protein

Beef-Pork-Chicken-Fish-Mutton-Lamb-Eggs-Milk products-Beans-Grains-Nuts

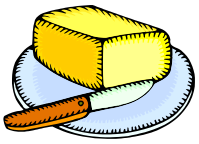


People living with HIV need to eat protein every day. As we said before, this is important for your muscles and to help prevent weight loss. Protein is found in meats and milk based foods. You can also get protein from dried beans, peas, lentils, peanuts or soya. These foods can be a very economical way of getting enough protein, they are often much cheaper than meat or milk products.

Fats and oils

Butter-Lard-Margarine-Cooking oils-Cream-Mayonnaise

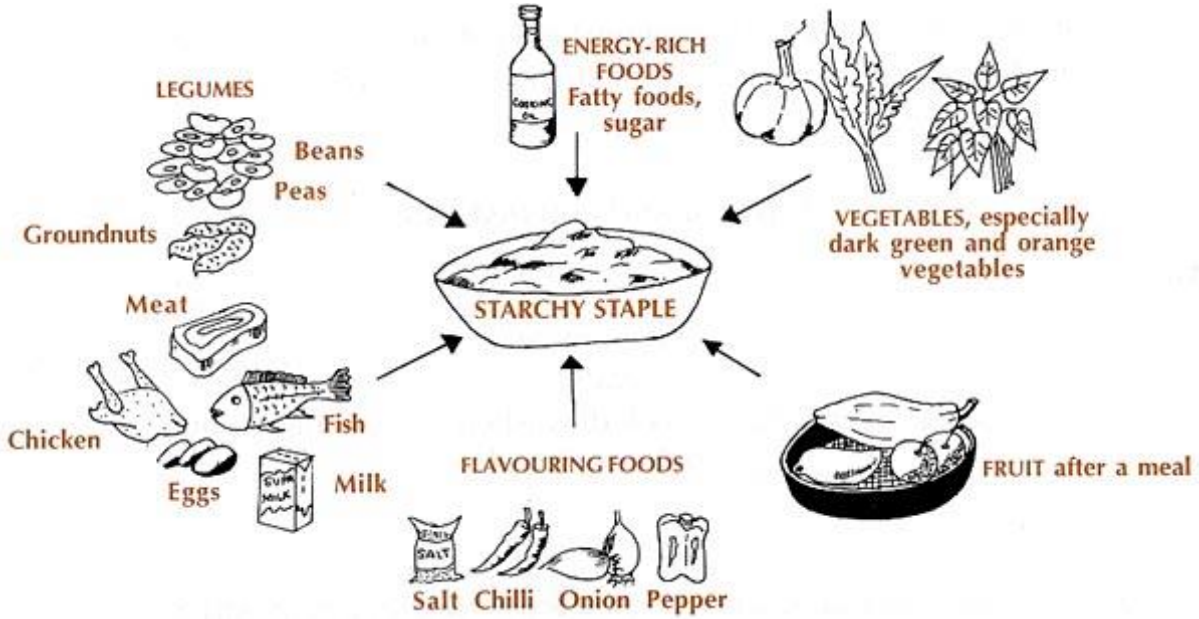
Fats and oils are also an important part of a healthy diet. These foods provide energy, like the starchy foods.



This does not mean you can eat as much as you like of these foods, but they should make up a portion of your diet. These foods can be used to increase your weight if you have been sick with an infection and lost weight.

How do I put it all together?

A balanced way of eating is for each meal to include two portions of starch + one portion of vegetables + one portion of fruit + one portion of protein. The fat portion of the food is included as part of the cooking (if you use oil) or if you put butter or oil on your food.



A balanced meal

"I find it hard to eat well!"

Now that you know what you should be eating let's talk about why people living with HIV may be struggling to eat enough. The reasons for not eating enough could be that they do not want to eat because they just don't feel hungry or because they are too tired to eat or they are too worried to eat or they feel like they will vomit if they eat, or they have diarrhoea or they have sores in their mouth which hurt when they eat or food just doesn't taste good any more. The next section gives ideas on ways to manage these problems.

"I'm not hungry"

On the days when you feel like eating, make sure you eat well to make up for days when you might not be eating so well. On the days when you do not feel like eating try to eat small meals more often, maybe 6 times a day. Eat in a relaxing place, maybe with a friend. Keep small snacks with you in your bag or next to your bed so that if you wake up or suddenly feel hungry you can eat straight away. Make sure these snacks have lots of energy in them (are complex sugars). Make sure you have your favourite foods to eat, even if it's just a little bit it helps.

"I get full too quickly"

You might be trying to get all your food at one meal. Try to eat five or six times a day. When you do eat, make sure its food with lots of energy and protein. Don't eat foods without energy first and then feel too full for important foods.

"Food doesn't taste so good"

Infections in the mouth or medicines can change the way food tastes. Sometimes you may have a bitter taste or a taste of metal in your mouth. If you have thrush, ask your doctor for medicine for this. You can also rinse your mouth with a mixture of 1 teaspoon of baking soda in a glass of water. DO NOT swallow this, rinse your mouth and spit it out. Try cleaning your teeth and your tongue before you eat. If you have a taste of metal in your mouth, try to drink orange juice or another tart drink.

"Eating makes me want to vomit"

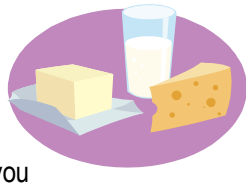
Wanting to vomit when you eat can be because of an infection or a side effect of the medication. Eating smaller meals helps (5 or 6 meals a day) – it is important to know that nausea or the feeling that you are going to vomit is often worse when your stomach is empty. Food with lots of spices or fats and food or drink with caffeine can irritate your stomach and make you feel sick. Salty and dry food might help (bread or crackers). If the smell of food makes you feel sick, ask someone else to cook, and also make sure there is lots of fresh air where the cooking is being done so that the smell clears quickly. Don't eat your favourite foods when you feel sick, you don't want to start thinking that your favourite foods make you feel sick. If you think your medicine is making you feel sick, ask your doctor or pharmacist about the best time to take the medicines which might help. You can also ask your doctor for medicine which will help to stop the feeling of nausea.

"I have diarrhoea"

Diarrhoea can be caused by the virus, by the medicines or by stress or other infections. When you have diarrhoea, your body is not getting the food that it needs, even if you are eating it, your body cannot absorb it. When you have diarrhoea, your body is also not getting enough fluids. You need to make sure you are getting enough liquid when you have diarrhoea to make sure that you don't get dehydrated. Go to the section on managing symptoms of HIV/AIDS for more information on how to manage diarrhoea. Remember, if you have diarrhoea for more than a week, you must go to your clinic for treatment.

"I feel sick if I eat dairy products"

Some people living with HIV find that drinking milk or eating milk products makes them feel sick. This is because the virus can affect a chemical in your intestine which you need to absorb milk. If this chemical is not present, you may feel bloated or get diarrhoea after eating milk products. This is called lactose intolerance. If this is happening to you, then you need to avoid eating milk products. Sometimes this reaction will get better; you might find that in a few months you could try a milk product again and not have the same reaction. This would mean that your body now has enough of the chemical it needs and you can resume eating milk products.



"My mouth is dry / I have sores in my mouth / chewing and swallowing hurts"

A dry mouth might be a side effect of medications. Sores and pain in the mouth can be from infections. You can help this by avoiding smoking and drinking alcohol as these irritate your mouth and throat. Eat softer food, if you mash your food or make soup as this will be easier to swallow. Try not to eat food with a lot of spices or drink fizzy drinks if your mouth is sore. These can make your mouth burn more. Eating cold food like ice cream or sucking on an ice block can help to numb your mouth. If your mouth is sore, try to drink through a straw. Rinse your mouth often and keep a bottle of water next to your bed so that you can rinse your mouth during the night.

Managing Eating Problems

- Try to eat at least 5 times a day – 3 meals and 2 snacks.
- Eat energy food first.
- Keep snacks with you to eat as soon as you feel hungry.
- Drink 6 glasses of juice and water a day.
- Drink rehydration fluid after every bout of diarrhoea.

Now that we have discussed how we should be eating and ways of managing eating problems, let's look at how to keep our food safe.

How do I keep my food safe?

If we don't pay attention to our food, where we get it from, how we store it and how we prepare and cook it, the food may become contaminated and make us sick. This is very important for the person living with HIV because you are more vulnerable to illness. There are simple ways to keep your food safe.

Storing and preparing food safely

- Read food labels carefully when you are shopping for food. Look for the "sell-by" and the "use-by" dates. Do not buy them if the "sell-by" date has already passed, do not buy if you are not sure that you will eat it before the "use-by" date.
- Don't buy food if the packaging is damaged
- Storing food properly is important to keep it safe. Food that you buy from the fridge or freezer section of a shop needs to be put into a fridge or freezer as soon as possible unless you are going to cook or eat it straight away.
- If a fridge or freezer is not available please buy food more regularly from the shops if this is feasible or buy longer lasting fruit and vegetables.
- Write on the packages of food the date you bought them so that you can keep track of how long you have had it. Remember food that can make you sick doesn't always look or smell bad.
- If you want to keep leftover food, store it in a container with a tight lid and put it into a fridge or freezer immediately (if available).
- If you have leftovers in the fridge you must eat them within 2 days. Leftovers that have been in the fridge for more than 2 days MUST be thrown away - even if they look and smell OK! If you do not have a fridge it is better to make fresh food daily.
- Always wash your hands before preparing food. Wash your hands again after handling any raw food.
- Wash up all your cutlery and crockery in HOT soapy water.
- If you have eaten food that has made you sick it is important that you clean all equipment and surfaces in the kitchen which that food might have touched. You can clean it using a mixture of 1 tablespoon of bleach in a litre of water.
- Never eat raw meat, chicken or fish of any kind.
- Make sure all meat is well cooked – no red meat of any kind.
- When you buy eggs make sure none have cracked shells. Keep them cold.
- Never eat any dish with raw eggs
- Use only pasteurized milk and milk products
- Wash all fruit and vegetables
- Keep fruit and vegetables in the fridge (or a container to keep longer lasting fruit uncontaminated).

Action Plan Form

Think about your eating habits. Use this form to come up with a plan to improve ***one*** thing about your nutrition.

Be sure your action plan includes:

What you want to do

How much you are going to do

When you are going to do it

How many days a week you are going to do it

For example: This week, I will walk (*what*) around the block (*how much*) before lunch (*when*) three times (*how many*).

This week I will:

_____*(what)*

_____*(how much)*

_____*(when)*

_____*(how many?)*

How confident are you that you can complete this action plan?

Not at all confident	| 1	| 2	| 3	| 4	| 5	| 6	| 7	| 8	| 9	| 10	Totally confident

Keep a record of how you did:

	I Plan to…..	**I did…..**
Monday		
Tuesday		
Wednesday		
Thursday		
Friday		
Saturday		
Sunday		

Exercise Diary

Keep using the exercise diary to keep track of your exercise goals from week one. You may want to start increasing your exercise plan.

Start off by writing down your goal.

Write down here what you want to be able to do: _____

Now, what do you want to be able to do *this week* which will help you to reach your goal?

Remember from your action plan to include:

What you want to do

How much you are going to do

When you are going to do it

How many days a week you are going to do it

For example: This week, I will walk (*what*) around the block (*how much*) before lunch (*when*) three times (*how many*).

This week I will:

_____ *(what)*

_____ *(how much)*

_____ *(when)*

_____ *(how many?)*

	Exercise Planned	**Exercise I did...**	**How did I feel? Do you need to change anything?**
e.g.	*20 mins in a.m. after breakfast and in p.m. after supper*		*Very tired by the second session, I'm going to cut it down to morning only for this week.*
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			

Week 6: Continuing as a Successful Self-Manager

Over the last six weeks you have learnt many skills which will help you to live positively with your condition. Research tells us that people living with any chronic disease who follow these steps have better quality of life, have fewer sick days and have better disease control. This is true for people living with high blood pressure, HIV/AIDS, cancer or depression. You have learnt how to be a positive self-manager by being able to solve problems and set goals for yourself so that you can move forward with your life. You have learnt about the importance of exercise. How exercise can make you feel better, what exercises you should do and you have been doing those exercises too! You have learnt about the common symptoms that trouble people living with HIV and you have learnt how to manage these symptoms. You have learnt about pain, what might be causing pain and how to treat and manage any pain you may have. You have learnt about food and eating well and how to make sure that your food is safe. With all of these you have also had the chance to practice doing things differently and to think about how this has made you feel.

Action Planning for the Future

Now it is time to think about the future. People with long term illnesses often worry about what will happen if they get very sick, how they will manage their lives; how they will they look after themselves or their families. Worrying about these things can also make people feel sad, angry or depressed and helpless. These emotions may make everything feel even more difficult than they are. By working through this book you have already started to deal with these emotions. You have increased your knowledge and this is one of the main ways that we manage fear. If we are afraid of something, knowing more about it helps us to tackle the fear. If you know more about it, you can make a plan around it and making a plan helps us to get a sense of control over the very thing that we are afraid of.

Planning for the future means thinking about the things that might happen to you in the future and planning for them. You may never ever need to use the plan as the things that you worry about may not happen, but, having a plan will help you to worry less about these things and stay in control should they happen. You can use the action planning forms you have been using in this workbook to think about the things which worry you about the future. You can then start making a plan about what you want to do if these things happen. If you are not sure about making a plan, you may want to talk to different people who might be able to help you with this.

Step 1:

To be able to plan for the future, you need to decide *what* it is that you are worried about happening. This can be the hardest step to think about. For example you might be feeling very sad and depressed. First you need to think about why you are feeling that way. It might be that you are worried about not being able to look after your family if you become ill, or you may be worried about making someone else ill, or you may be worried about not being able to look after yourself, or you may be worried about dying. Once you have identified what it is that worries you and makes you feel sad, depressed, angry or afraid then you can start to make a plan to deal with it. This will help you to feel less sad, depressed, angry or afraid.

Write down here some of the things that might happen in the future that you worry about:

1) _____

_____

2) _____

_____

Step 2:

Now that you have identified some of the things which worry you, you can start to think about different ways to manage these things. If you were worried about becoming ill and not being able to look after yourself, write down a list of things that you would need help with. Then write down who you could ask to help you with those things. The people who can help might be family, friends, social workers, counsellors, nurses, physiotherapists, occupational therapists or doctors. If you are not sure who could help you, you may want to talk to someone you trust to help you identify who could help.

Write down here three different things you could do to help plan for the things in the future that you worry about:

1) _____

2) _____

3) _____

There are many organisations and people who you can approach for help in planning for the future. These organisations include the Treatment Action Campaign (TAC), the Family and Marriage Society of South Africa (FAMSA), your church, the AIDS consortium; the Aids Law Project (ALP), the National Association of People living with HIV/AIDS (NAPWA) as well as the health care practitioners at your local clinic. The contact details for these organisations are included at the end of this section.

Once you have completed Step 2 and written down three different things you could do to help plan for the things in the future that you worry about, choose the one which seems to suit you the best (this might be one which is easier or is cheaper or you know has worked for someone else). Now use this action plan form to work out what you will do if the thing which you worry about happening should happen. You can use this method to plan for any of the things which worry you.

Action Plan Form for Future Worries

I am worried that in the future I will not be able to:

_____

_____

My plan to manage this if it happens is to:

_____

_____

_____

_____

_____

_____

_____

_____*(what, who, how, when?)*

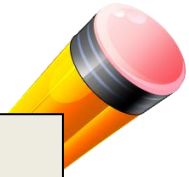
How confident are you that you can complete this action plan? *(remember you are aiming for 7 out of 10 on the confidence line)*

_____

Not at all	|	|	|	|	|	|	|	|	|	|	Totally
confident	1	2	3	4	5	6	7	8	9	10	confident

Moving forward:

Over the last 6 weeks you have learnt many things about how to live with a chronic illness like HIV/AIDS. You have learnt about the disease and how to be a successful self-manager. This does not mean that you should be managing your health on your own. What it does mean is that you now have the ability to manage your health and your life as part of the health team. Remember you are not alone but are part of a team of people whose aim is to help you get the most out of life. We encourage you to keep using the skills you have learnt in this workbook to live positively. There are extra "Action Plan Forms" and "Exercise Diaries" in the back of the workbook for you to use. Try to keep using these forms to help you remain active and give you a sense of purpose and accomplishment in your life. Being active and involved, using the skills you have learnt in this workbook are important steps in helping you achieve the best quality of life you can. In the box write down some of the important changes you have made in your life over the past few weeks.



Changes I have made in my life:

Now, your final task is to think about changes you still want to make in your life. Remember, this is about getting the most out of life, increasing your quality of life. Are there still some things missing in your life, things that you would still like to be able to do? In the box below, write down some of the things that are still missing. You can use this list to keep working on your goals from now on.

Things that are still missing in my life:

You have now completed this workbook. By working through this workbook you made an important commitment to yourself. You have chosen to spend time looking after yourself and you have taken steps to overcome the many challenges that people living with HIV/AIDS face. Do not put this workbook away; keep it somewhere safe where you will be able to review it from time to time. We all forget things at times and it is useful to be able to look back and remind ourselves of things we may have forgotten. We can also look back and see how far we have come. We hope that the knowledge and the skills you have learnt by using this workbook will continue to have a positive effect on your life.

Useful Organisations:

Zithulele ARV Clinic and Outreach programme (www.jabulanifoundation.org)

Jabulani Office (Zithulele Village): 081 370 1041

Philani - Mentors Mothers Programme (www.philani.org.za)

Zithulele Office (Zithulele Village): 0739048243 (Ncedisa)

0732250751 (Nomsa)

Stop Stock Outs – Monitoring Essential Medicines Consortium (www.stockouts.org/index)

Reporting Stock Outs: 084 055 7867(STOP) (SMS, Please Call Me, Phone, WhatsApp)

(email) report@stockouts.co.za

Treatment Action Campaign (TAC) (www.tac.org.za)

National Office (Cape Town): 021 422 1700

Eastern Cape Office (Lusikisiki): 039 253 1951

EC Satellite Office (East London): 073 636 1373

Family and Marriage Society of South Africa (FAMSA) (www.famsaorg.co.za)

East London Office: 043 743 8277

AIDS Consortium (www.aidsconsortium.org.za)

National Office (Gauteng): 011 403 0265

National Association of People Living with HIV/AIDS (NAPWA) (www.napwasa.org)

Eastern Cape Office (East London): 043 760 0333

Additional Reading

The information is this workbook is based on several sources of information. If you would like to read more on any of these topics we suggest you explore these:

Living Well with HIV & AIDS; Gifford A.L.; Lorig K; Laurent D; Gonzalez V (3rd edition) Bull Publishing Company, Boulder Colorado2005

Self-management of Long-term Health Conditions: A handbook for people with chronic disease. Expert Patients Programme Community Interest Company . Bull Publishing Company, Boulder Colorado 2007

Manage your pain. Nicholas M, Molloy A, Tonkin L, Beeston L ABC Books, Sydney 2000

HIV in our lives: a book of information sheets for clinics. Treatment Action Campaign, Cape Town, 2007

Appendix E: Positive Living Course Participation Agreement English and Xhosa versions

School of Health & Rehabilitation Sciences

Divisions of Communication Sciences & Disorders · Nursing & Midwifery · Occupational Therapy · Physiotherapy

Positive Living Course Participation Agreement

I, _____ , understand that all discussions which take place during the 'Positive Living' course are confidential and shall not be spoken of outside of this group. I agree to maintain the trust of those participating in the course with me.

I agree to attend all six (6) sessions of the course. I understand that this is for my own benefit. For any reason if I am unable to attend a day of the course I will get in contact with my peer-leader ([redacted] - [redacted]) or the researcher (Kirsty Jackson – 0826849760).

I understand that this course is aimed at helping me to cope better with living with HIV/AIDS. I understand that a major part of the course is setting goals and working towards them. I will work towards these goals weekly and share my achievements. Working towards my goals and sharing these achievements are of benefit and encouragement to me and those participating in the group. Another major part of taking part in this group is exercising. I agree to participate in this.

Signed: _____ Date: _____

Inxaxheba kwisifundo 'Ukuphila Ngokuqinisekileyo' Isivumelwano

Mna,_____, ndiyaqonda ukuba zonke iingxoxo ezenzeka ngexesha lesifundo 'Ukuphila Ngokuqinisekileyo' ziyimfihlo yaye akunakuthethwa ngazo ngaphandle kweliqela. Ndiyavuma ukuthembakala kwabo bathatha inxaxheba kwisifundo kunye nam.

Ndiyavuma ukuza kuzo zontandathu(6) iintlangano zesifundo. Ndiyaqonda ukuba oku kuyinzuzo kum. Ukuba kuthe kwenzeka, nangasiphi na isizathu, ndingakwazi ukubakhona kusuku oluthile lwesifundo, ndiyakuqhagamshelana nenkokheli yam ([redacted]) okanye umphandi-lwazi (Kirsty Jackson-0826849760).

Ndiyaqonda ukuba injongo yesi sifundo kukuba sincede mna ndikwazi ukumelana ngcono nokuphila nentsholongwane kagawulayo okanye ugawulayo.
Ndiyaqonda ukuba eyona nto ingundoqo kwisifundo esi kukuzenzela izicwangciso futhi ndilandelele ngokuzifezekisa. Ndiyakusebenza ukuphumelelisa ezi zicwangciso qho ngeveki ndakugqiba ndabelane nabanye ngezinto ezithe zayimpumelelo. Ukusebenzela ukuphumelelisa izicwangciso nokwabelana ngempumelelo yam kuyinzuzo kum nakwabo bathatha inxaxheba kwiqela. Omnye undoqo ekuthatheni inxaxheba kwesi sifundo ngumthambo. Ndiyavuma ukuthatha inxaxheba koku.

Isayinwe: _____ Umhla: _____

Appendix F: ACSM Health/Fitness Screening

Allocated No.:

AHA/ACSM Health/Fitness Facility Preparticipation Screening Questionnaire

Assess your health needs by marking all *true* statements.

History

You have had:

___ A heart attack
___ Heart surgery
___ Cardiac catheterization
___ Coronary angioplasty (PTCA)
___ Pacemaker/implantable cardiac defibrillator/rhythm disturbance
___ Heart valve disease
___ Heart failure
___ Heart transplantation
___ Congenital heart disease

Symptoms

___ You experience chest discomfort with exertion.
___ You experience unreasonable breathlessness.
___ You experience dizziness, fainting, blackouts.
___ You take heart medications.

*If you marked any of the statements in this section, consult your physician or other appropriate healthcare provider before engaging in exercise. You may need to use a facility with a **medically qualified staff**.*

Other health issues

___ You have diabetes
___ You have or asthma other lung disease.
___ You have burning or cramping in your lower legs when walking short distances.
___ You have musculoskeletal problems that limit your physical activity.
___ You have concerns about the safety of exercise.
___ You take prescription medication(s).
___ You are pregnant.

Cardiovascular risk factors

___ You are a man older than 45 years.
___ You are a woman older than 55 years, you have had a hysterectomy, or you are postmenopausal.
___ You smoke, or quite within the previous 6 mo.
___ Your BP is greater than 140/90.
___ You don't know your BP.
___ You take BP medication.
___ Your blood cholesterol level is >200 mg/dL.
___ You don't know your cholesterol level.
___ You have a close blood relative who had a heart attack before age 55 (father or brother) or age 65 (mother or sister).
___ You are physically inactive (i.e., you get less than 30 min. of physical activity on at least 3 days per week).
___ You are more than 20 pounds overweight.

*If you marked two or more of the statements in this section, you should consult your physician or other appropriate healthcare provider before engaging in exercise. You might benefit by using a facility with a **professionally qualified exercise staff** to guide your exercise program.*

___ None of the above is true.

You should be able to exercise safely without consulting your physician or other healthcare provider in a self-guided program or almost any facility that meets your exercise program needs.

Balady et al. (1998). AHA/ACSM Joint Statement: Recommendations for Cardiovascular Screening, Staffing, and Emergency Policies at Health/Fitness Facilities. *Medicine & Science in Sports & Exercise*, *30*(6). (Also in: *ACSM's Guidelines for Exercise Testing and Prescription*, 7th Edition, 2005. Lippincott Williams and Wilkins http://www.lww.com)

www.acsm-msse.org/pt/pt-core/template-journal/msse/media/0698c.htm

Appendix G: Information sheets and Informed Consent form

Appendix G/1: Information sheet – Positive Living Group

Information sheet – Positive Living Group

Study Title: **Efficacy of a multimodal approach to managing pain in rural amaXhosa women living with HIV/AIDS compared to a therapeutic relationship**

Name of researcher: Kirsty Jackson, Masters Physiotherapy Student BSc (Phys)
Name of supervisor:
Romy Parker, Bsc(Phys) Bsc(Med)(Hons) Ex.Sci(Phys) Msc(Pain) PhD(Psych)
Senior Lecturer and Deputy Head of Division (Physiotherapy)
Institution:
University of Cape Town, Division of Physiotherapy

What are we doing and why?

I am a student at the University of Cape Town. I'm doing a degree in MSc Physiotherapy. I want to learn about what helps amaXhosa women living with HIV/AIDS cope better. What helps you enjoy life more? What helps you do more activities? What helps you to take part in your family and community more. I want to find out whether knowing more about HIV and learning ways to manage symptoms of HIV helps you. To learn about this, we are asking some people to take part in this study. In the last few years a similar study was done in a South African city. The researcher found a useful way of helping amaXhosa women in cities or towns cope more with living with HIV/AIDS. We now need more research to find out if this way will be useful here. Will this way be useful in rural amaXhosa women living with HIV/AIDS.

Why have you been asked?

You have shown interest in the study. You also meet the requirements which are needed to take part in the study. We are including people who are:

- amaXhosa
- HIV positive
- aged between 18 and 40 years
- attend one of the two clinics included in this study
- answered "yes" to the question: "Throughout our lives most of us have had pain from time to time (such as minor headaches, sprains, toothaches). Have you had pain other than these everyday kinds of pain during the last week?".

We are looking for 24 people from each clinic to take part.

What will taking part involve and what will you need to do?
If you agree to be part of the study you will first be asked questions. Then you will be asked to do a few actions or tasks. This should take 30-45 minutes. Your time is important and we understand that this is a long time. We will be very thankful for your time. It will help us to find out more about how we can help amaXhosa women living with HIV to cope better. Hopefully with time it will bring about change.

You have been placed in one of two groups. There was an equal chance of being put into either group. Each group will do something different. It doesn't matter which group you are in. We are doing the study to find out if either of the things the two groups do is better than the other. At the end of the study if what one group does is found to be better than you will have an opportunity to take part in what that group did.

You are in the group which takes part in the 'Positive Living' intervention. This is a treatment where you learn how to manage the symptoms you get from having HIV. You will take part in a group to learn these things and will do exercise too. You will also be asked to agree to come to six *buya-dates* to learn the most out of this group. The group will be led by a peer-leader and will be run at a venue close by to the clinic for two hours every Wednesday morning between 10am and 12am or afternoon between 1pm and 3pm for six-weeks. Each person in the group will be asked to sign a document/contract to keep what is shared in the group safe and to not allow what people said and their secrets to be shared with people outside the group. The peer-leader, who also has HIV/AIDS, will help the group to talk about different tops and make a plan of action and do some gentle exercise that might change how you cope with living with HIV. There is a workbook called 'Positive Living', which has information which will be talked about in the group over six sessions. This workbook will be given to each person who takes part in this group and you can have it in isiXhosa and English.

During the group and after the group you will be asked to come to the clinic for follow-up dates. You will be asked to come after 4 weeks, 8 weeks, 12 weeks, 24 weeks and 1 year after the study starts. We will need to talk to you and remind you of follow-up dates during the year. For this reason, we will ask for your cellphone number. During the study, you must not tell anyone else that you are taking part in this group. You must not tell anybody what you are doing in the group. You must not tell people in the community or the person who sees you for follow-ups on how you are doing during the study.

What if something goes wrong

If you have certain health problems, exercise may not be safe for you. Someone asked you questions about your health to make sure that it is safe for you to exercise. If it is not safe for you to exercise you would not be allowed to take part in the study. If it becomes unsafe for you to exercise we will refer you to someone to help with your healthcare.

Being in a group means that you may share personal information. You might not want to share this information with people outside of the group. Sharing personal information may be something that is unsafe for you to do. For this reason, documents (contracts) will be signed by the peer-leaders and group members. These documents will try to stop any personal information from being shared outside of the group. This will help to make the group safer to share information in. There is a chance that if you take part in this study somebody might find out that you have HIV. However, steps have been taken to prevent this. You will not meet at the clinic for follow-ups and your workbook does not have anything which is associated with HIV/AIDS.

We have promised that we will not give anyone your information. We will not share what you have told us with anyone else without asking you. There are only a few people who may see or hear what we have learnt from you. These people are the researcher, the research supervisor and members of the Human Research Ethics Committee. The Human Research Ethics Committee are a group of people who keep people taking part in studies safe. The researcher will not include your name or anything which identifies you when writing about what has been learnt.

You will also be protected if you have an injury during the study by the University of Cape Town (UCT). This is the institution behind the running of this study. UCT has insurance cover (money) to pay for medical costs if you get injured or have unpleasant side-effects because of taking part in this study. This plan has been made to follow the South African Good Clinical Practice Guidelines. These guidelines were written by the Department of Health in 2006. The ideas in these guidelines come from the Association of the British Pharmaceutical Industry Guidelines (ABPI). You will not have to show proof that the University is at fault for the injury. UCT will take responsibility without proof. You must immediately let the study health professional know if any injury happens to you during the study.

However, UCT **will not be responsible by law** in all situations. This means they do not have to pay for medical costs if the following happens:

Any loss, injuries and/or harm that happens to you because of

- The use of unauthorised medicine or substances (not having full permission or being allowed to use these) during the study
- Any injury that happens because you have not followed the rules or instructions that the study doctor/ health professional gives you
- Any injury that happens from not responding or acting on a side effect or reaction to the study medication as best as one can*
- An injury that happens from negligence (not taking proper care) on your part*

By taking part in the study you are still allowed to go the law/ courts to claim for compensation. You can do this if an injury happens which you can prove was because of taking part in the study. This right will be protected and made sure of. Please be aware that most of the time you will be paid the money for to cover medical costs as a full settlement. This means that this will be the total money you will receive even if taken to court.

If you want further information about these guidelines you may ask for a copy.

What will taking part in this study help you with?

It is not clear exactly how the study will help you. This is why we are doing the study. We want to find out if the 'Positive Living' intervention helps amaXhosa women with HIV in a rural context. We hope that the information learnt from this study will help people living with HIV/AIDS cope better in the future. If the results show how to help these people then we would like to tell people who can change how the government and health care workers help HIV positive people. These people would include organisations, local health institutions, or government. All these people work together to help people living with HIV/AIDS. By sharing results, we can help them to improve services for people who are HIV positive to cope better. Your name and personal information will never be given to these organsations or government. Your name will always be kept safe.

Remember that if we find that one of the groups got more help from the study the other group will get offered that treatment. Therefore, if the study does have a benefit then you will have a chance to benefit from it.

Do you get anything if you commit to take part in the study?

You will not get money or get payed for taking part in the study. However, your transport costs to the hospital and back home will be paid for whenever you visit the clinic to take part in this study. You will be given biscuits and a juice at each two-hour session during the 'Positive Living' intervention. At the end of the intervention you will get a document (certificate). This document will say to say that you have completed the 'Positive Living' intervention.

Taking part in this study is voluntary

It is your choice whether you would like to take part in this study or not. Nobody can tell you that you have to take part in the study. If you do agree and commit to take part in the study you will always have the choice to not answer questions asked. You cannot be forced to do tasks asked or come to sessions or follow-up dates. Your actions are your choice. Taking part is a choice during the whole study. If during the study you choose that you do not want to do something asked of you or you do not want to take part any longer you will not be treated any differently.

You will not be treated any differently if you decide not to be part of the study at all either. Those who take part in the study will not be given any privileges. They will not be treated differently in hospital and clinic services.

Will my information be safe?
The information you give us and what we learn from you will be kept safe. Nobody will be able to get that information except the researcher, research supervisor and members of the Human Research Ethics Committee. Other than these people nobody will know that the information and what we learn comes from you. Your name will not be included with information.

What we learn can only be used for making services better for amaXhosa women living with HIV/AIDS. You will be contacted and asked to agree and sign (consent) should the information be helpful for another use.
If you have **any questions or worries,** please contact Kirsty Jackson (082 684 9760). You may use a please-call me to make contact. You make ask questions at any time during the study.

You are also welcome to contact the research supervisor or the chairperson of Human Research Ethics Committee should you have concerns or questions about your rights or welfare as participants.

Research supervisor:	**Human Research Ethics Committee Chairperson:**
Dr. Romy Parker	Professor Marc Blockman
021 406 6571	021 406 6492

Iphepha-nkcazelo – Positive Living Group

Isihloko sesifundo: **"Isifundo esifuna ukujonga ukuba iindlela ezohlukenenyo zokuncedisa ukumelana neentlungu ezifumaneka ngenxa yokuphila nogawulayo kwabasethyini bamaXhosa abaphila nentsholongwane kagawulayo okanye ugawulayo".**

Igama leresearcher: Kirsty Jackson, Masters Physiotherapy Student BSc (Phys)
Igama lesupervisor:
Dr Romy Parker, Bsc(Phys) Bsc(Med)(Hons) Ex.Sci(Phys) Msc(Pain) PhD(Psych)
Senior Lecturer and Deputy Head of Division (Physiotherapy)
Iziko:
University of Cape Town, Division of Physiotherapy

Senzantoni kwaye kutheni?

Ndingumfundi kwi Dyunivesi yase Kapa. Ndenza imfundo enomsila kwi MSc Physiotherapy. Ndifuna ufunda ngezinto ezinceda abasethyini bamaxhosa abaphila nentsholngwane kagawulayo ukuba baphile ngcono. Yintoni ekuncedayo ukuba wonwabele ubom ngakumbi? Yintoni ekuncedayo ukwazi ukwenza imisebenzi ngakumbi? Yintoni ekuncedayo ukwazi uthabatha inxaxheba kusapho lwakho nasekuhlaleni ngakumbi? Ndifuna ukufumanisa ukuba ingaba ukwazi ngakumbi ngentsholongwane kagawulayo kwaye ukufunda iindlela zokulawula okanye ukumelana neempawu zentsholongwane kagawulayo kuyakunceda na? Ukufunda ngoku sicela abanye babantu bathathe inxaxheba kolufundo. Kwiminyana embalwa endlulileyo ofundo olofana nolu lwake lwenziwa kwisixeko saseMzantsi Africa. Umphandi wafumanisa indlela eluncedo yokunceda abasethyini bamaxhosa abasezixekweni okanye ezidolophini bamelane ngakumbi nokuphila nentsholongwane kagawulayo/ ugawulayo. Sifuna kengoku uphando olumandla ukufumanisa ukuba lendlela iyakuba luncedo na apha. Ingaba lendlela iyakuba luncedo emaphaandleni kwabasethyini abaphila nentsholongwane kagawulayo/ gawulayo.

Kutheni uceliwe?

Ubonakalise umdla kwizifundo. Kwaye unazo zonke izinto eziyimfuneko ezifunekayo ukuze uthabathe inxaxheba kwisifundo. Siquka nabantu aba:

- amaXhosa
- Abanentsholongwane kagawulayo
- Abaphakath kweshumi elinesibhozo namashumi amane eminyaka
- Abake baya kwenye yeekiliniki ezimbini kuquka nolufundo
- Uphendule “ewe” embuzweni : “Kubo bonke obomi bethu unintsi lwethu sike seva iintlungu amaxesha ngamaxesha (njengentloko engabhekelephi ebuhlungu, sprains, amazinyo abuhlungu). Uke wanentlungu ngaphandle kwezi ntlobo zemihla ngemihla kwezinyanga zintathu zidlulileyo?”.

Sikhangela abantu abangamashumi amabini anesine kwi kiliniki nganye ukuba bathathe inxaxheba.

Oku kwenzekayo kuyawube kuquka ntoni kwaye kuyawfuneka wenze ntoni?

Ukuba uyavuma ukuba yinxalenye yesisfundo uyawuqala ngokubuzwa imibuzo. Kengoku uyawucelwa wenze izinto ezimbalwa okanye imisebenzi. Oku kungathatha amashumi amathathu ukuya kumashumi amane anesihlanu. Ixesha lakho libalulekile kwaye siyaqonda lixesha elide eli. Siyawukulibulela kakhulu ixesha lakho. Kuyawusinceda ufumanisa ngakumbi ukuba singabanceda kanjanina abasethyini bamaxhosa abaphila nentsholongwane kagawulayo baphile bhetele. Ngethemba exesheni iyawuzisa utshintsho.

Ubekiwe kwelinye okanye amabini amaqela. Bekukho ithuba elilinganayo lokuba ubekwe nakweliphi na iqela. Iqela ngalinye liyawukwenza into eyahlikileyo. Akukhathaliseki ukuba ukwelipi na iqela. Senza isifundo ukufumanisa ukuba ingaba into eyenziwa ngalamaqela mabini ingcono na kuneyenziwa ngamanye. Ekupheleni kwesifundo ukuba okwenziwa lelinye iqela kufunyaniswe kungcono kengoku uyawufumana ithuba lokuthatha inxaxheba kokuyawube kusenziwa liqela.

Useqeleni elithabathea inxaxheba kwi “Phila Ngokuqinisekileyo” intervention. Olu lunyango apho ufunda ngeendlela zokumelana neempawu ozifumanayo ngengxa yentsholongwane kagawulayo. Uyawuthabatha inxaxheba eqeleni ukuze ufunde ezizinto uyawukwenza nemithambo kananjalo. Kwaye uyawucelwa ukuba uvume ukubuya kuzo zontandatho iideyithi zobuya ukuze ufunde okunintsi kweliqela. Iqela liyakukhokelwa ngumcebisi okhokeleyo kwaye iyakuqhutywa kwindawo ekufutshane nekiliniki kangangee yure ezimbini qho kusasa ngoMvulo phakathi kwentsimbi yeshumi neyeshumi elinambini okanye emva kwemini phakathi kwentsimbi yokuqala neyesithathu kangangeeveki ezintandathu. Umntu ngamnye eqeleni uyawukucelwa ukuba atyikitye incwadi okanye isivumelwano sokugcina yonke into ebithethwa eqeleni iyimfihlo, kwaye kungavunyelwa ukuba okuthethwe ngabantu neemfihlelo zabo kwabelwane ngazo nabantu abngaphandle eqeleni.

Umcebisi qela onentsholongwane kagawulayo/ugawulayo naye uyawuncedisa iqela ukuthetha ngezihloko ezahlukileyo enze necebo lento emayenziwe enze nemithambo elula egathsintsha indlela onokumelana ngayo nokuphila nentsholongwane kagawulayo okanye ugawulayo. Umcebisi qela uyawucela umntu ngamnye eqeleni ukuba enze umqweno wento acinga ukuba angayenza enomceda aphile ngcono. Kukho incwadi yokusebenza ebizwa ngokuba yi“Phila Ngokuqinisekileyo” eneenkcukacha ngokuyawuthethwa ngako eqeleni kwezi zifundo zithandathu. Lencwadi yokusebenza iyawukunikezwa kuye wonke umntu othabatha inxaxheba kweliqela kwaye ungayifumana ngesixhosa nangesingesi.

Ngexesha lendibano nasemva kwendibano kuyawucelwa umntu ngamnye ukuba uze ekiliniki ukulandelela iideyithi zokkuphinda ubonwe. Uyawucelwa ukuba uze emva kweeveki ezine ezisibhozo, ezilishumi elinambini, ezingamashumi amabini anesine kunye nonyaka emva kokuba isifundo siqalile. Kuyawufuneka sithethe nawe kwaye sikukhumbuze ngeentsuku zakho zobuya enyakeni. Ngenxa yesisizathu siyawucela iinombolo zenu zomnxeba.

Ngethuba lesifundo ungamxeleli umncedisi owenza imibuzo novavanyo kuwe ukuba ukwekiphi iqela. Ungabaxeleli ukuba ukwiqela le'Phila Ngokuqinisekileyo'.

Ukuba kukho into ehambe ngendlela engeyiyo

Ukuba uneengxaki ezithile zempilo, imithambo inganobungozi kuwe. Omnye umntu uyawukukubuza imibuzo malunga nempilo yakho ukuqinisekisa ukuba ukhuselekile ukuba ungenza imithambo. Ukuba awukhuselekanga ukuba wenze imithambo awuvunyelwa ukuba uthathe inxaxheba esifundweni. Ukuba kubanokungakhuseleki kuwe ukwenza imithambo siyawukukuthumelela kumntu ozakunceda ngokhathalelo lwempilo yakho.

Ukuba seqeleni kuthetha ukuba ungabelana ngeenkcukacha zakho eziyimfihlo. Ungangafuni ukwabelana ngeenkcukacha nabantu abangaphandle eqeleni. Ukwabelana ngeenkcukacha eziyimfihlo zakho kungayinto engakhuselekanga ukuba uyenze. Ngenxa yesosizathu iifomu (zesivumelwano) ziyakusayinwa ngumkhokeli qela (i-peer leader) namalungu eqela elo. Ezimpepha ziyakuzama ukunqanda nayiphi na inkcukacha eyimfihlo kungathethwa ngayo ngaphandle eqeleni. Oku kuyawukwenza iqela likhuseleke ukuthetha ngeenkcukacha zabo. Usethubeni lokuba xa useqeleni omnye umntu angafumanisa ukuba unenstholongwane kagawulayo. Sekunjalo amanyathelo athathiwe ukunqanda oku. Anizukuhlanganela kwiikliniki zamachiza entsholongwane kagawulayo ngeemini zendibano kwaye nencwadi yenu yokusebenza ayinayo kwanto eyayamene nentshlongwane kagawulayo okanye ugawulayo.

Sithembisile ukuba asisayi kunika mntu iinkcukacha ngani. Asisayi kwabelana namntu ngenithe nasixelela kona ngaphandle koba sicele imvume kuni. Kukho abantu abambalwa abanothi babone okanye beve ngesithe sakufunda kuni. Ababantu ngabaphandi, ababkhokeli baphandi, namalungu eHuman Research Ethics Committee. I-Human Research Ethics Committee liqela labantu abagcina abantu abathatha inxaxheba kwizifundo bekhuselekile. Uphando alusayi kuquka igama lakho okanye nantoni eyakuchaza okanye icacise wena xa kubhalwa ngokuthe kwafundwa.

Kwaye uyakukhuseleka ukuba uthe wanomonzakalo ngexesha lesifundo esenziwa yidyunivesiti yase Kapa (UCT). Le yimenko esemva kokuqhuba kwesifundo. I UCT inengxowa yokhuselo (imali) yokubhatala iindleko zonyango xa uthe walimala okanye ubenemiphumela engaqhelekanga ngenxa yothabatha inxaxheba kwesisisfundo. Elicebo lenzelwe ukulandela iSouth African Good Clinical Practice Guidelines. Lemiqathango yabhalwa lisebe lezempilo ngo2006. Imibono ngalomgaqo isuka kwi Association of the British Pharmaceutical Industry Guidelines (ABPI). Akusayi kufuneka ukuba ubonise ubungqina bokuba idyunivesiti isengxakini ngenxa yomonzakalo. I UCT iyawuthatha uxanduva ngaphandle kobungqina. Kuyawufuneka kwangoko wazise ingcali ngemfundo yezempilo eyaziwayo ukuba kuthe kwakho ingozi eyenzekayo kuwe ngethuba lesifundo. Kanjalo I-UCT ayisayi kubanxaxheba ngokomthetho kuzo zonke iimeko. Oku kuthetha ukuba abasayi kubhatala iindleko zonyango ukuba kwenzeke oku kulandelayo:

- Ukusebenzisa amachiza angavumelekanga okanye izinto (kungekho mvume iphelelelyo okanye ube uvunyelwe ukusebenzisa ezozinto) ngethuba lesifundo.
- Umenzakalo owenzeke ngenxa yokuba ungalandelanga imithetho okanye imiyalelo oyinikiweyo ngugqirha wesifundo okanye ingcali yezempilo.
- Nayipi na ingozi eyenzeke ngokungalandeli okanye ukwenza intshukumo ekhawulezileyo xa ubona ukuba amayeza owanikiweyo awakulungeli.
- Nawuphi na umonzakalo owenzeke ngenxa yokungakhathali (ukungathathi inkathalo eyiyo) kwindima yakho.

Ngokuthabatha inxaxheba kwisifundo usavumelekile ukuba ungaya egqwetheni okanye enkundleni uyokwenza ibango lomonzakalo. Ungakwenza oku xa umonzakalo othe wenzeka kuwe ungqina ukuba wenzeke ngenxa yothatha inxaxheba kwisifundo. Elilungelo liyakukhuselwa kwaye liqinisekiswe. Nceda qaphela ukuba amaxesha amanintsi uyawubhatalwa imali ukuze uhlawule iindleko zonyango ngokupheleleyo. Oku kuthetha ukuba le iyawukuba yimali epheleleleyo oyakuyifumana nokuba usise enkundleni.

Ukuba ufuna ingcombolo engakumbi ngalemigaqo ungacela ikopi.

Kuyakukunceda ngatoni okuyawuqhubeka kwesisifundo?

Akucacanga ncam ukuba esisifundo siyawkunceda kanjani, yiyo loonto senza isifundo. Sifuna ukufumanisa ukuba ngaba I“Phila Ngokuqinisekileyo” intervention iyabanceda na abasethyini bamaxhosa abanentsholongwane kagawulayo abasemaphandleni. Siyathemba ukuba iingcombolo ezifundwe kwesisisfundo ziyakubanceda abantu abaphila nentsholongwane kagawulayo okanye ugawulayo ukuba baphile bhetele ebomini. Ukuba iziphumo zibonakalisa ukuba singabanceda njani ababantu, ngoko singathanda ukuba singaxelela abantu abanotshintsha indlela urhulumente nabasebenzi bezempilo abanceda ngayo abantu abanentsholongwane kagawulayo. Ababantu bayakuquka imibutho, amaziko empilo asekuhlaleni, okanye urhulumente. Bonke ababantu bayasebenzisana ukunceda abantu abaphila nentsholongwane kagawulayo nogawulayo. Ngokwabelana ngeziphumo singabanceda baphuhlise iinkonzo ukwenzela abantu abaphila nentsholongwane baphile ngcono. Igama lakho neenkcukacha ngawe azisayi kunikezwa kulemibutho okanye kurhulumente. Igama lakho liyakuhlala ligcinwe likhuselekile.

Khumbula ukuba siye safumanisa ukuba elinye leqela lifumene uncedo olukhulu kwisifundo, elinye iqela liyakufumana ukunikezwa unyango. Ngoko ke ukuba isifundo siye saxhamla ngoko uyawufumana ithuba lokuxhamla kuso.

Kukho into esiyifumanayo ngokuzibophelela ekutheni inxaxheba kwesisifundo?

Awusayi kufumana mali okanye ubhatalwe ngothabatha inxaxheba kwesisifundo. Kodwa ke iindleko zakho zokhwela isithuthi ukuza esibhedlele nobuyela ekhaya ziyakubhatalwa ngalo lonke ixesha undwendwela ekiliniki uzothatha inxaxheba kwesisifundo. Uyakunikezwa amakhekhe nesiselo kuzo nzonke iiyure ezimbini zamahlelo ngexesha le“Phila Ngokuqinisekileyo” intervention. Ekupheleni kwe intervension uyawufumana incwadi (isatifiketi). Lencwadi iyawuthetha ukuthi uyigqibile I“Phila Ngokuqinisekileyo” intervention.

Ukuthatha inxaxheba kwesisifundo kukuzinikela

Lukhetho lwakho ukuba ungathanda ukuthatha inxaxheba kwesisifundo okanye hayi. Akekho umntu onokuxelela ukuba umele uthathe inxaxheba esifundweni. Ukuba uyavuma kwaye uyazibophelela uthatha inxaxheba kwisifundo lonke ixesha uyawubanalo ukhetho lokuba ungaphenduli imibuzo ebuzwayo. Awunakunyanzelwa ukuba wenze imisebenzi ekuthiwe yenze, okanye uze ezindibanweni, okanye kwiintsuku zophinda ubonwe. Iintshukumo zakho uyazikhethela. Uthatha inxaxheba kuzikhethela ngalo lonke ithuba lesifundo. Ukuba ngethuba lesifundo ukhetha ukuba awufuni ukwenza into oyiceliweyo okanye awusafuni uqhubeka nothatha inxaxheba awuyikuphathwa ngokwahlukileyo.

Awuyikuphathwa ngokwahlukileyo ukuba ugqiba ekubeni ungabiyonxalenye yesifundo kwawena. Abo bathabatha inxaxheba kwisifundo ubayi kunikwa kwangqwalasela. Abayikuphathwa ngendlela eyahlukileyo esibhedlele nakwiindibano zeekiliniki.

Ingaba iinkcukacha ngam zikhuselekile?

Iinkcukacha osinike zona ngawe nesithe sakufunda kuwe kuyakugcinwa kuyimfihlo. Akukho mntu uyawukwazi ukufumana ezonkcukacha ngaphandle komphandi, umkhokeli mphandi, namalungu eHuman Research Ethics Committee. Ngaphandle kwababantu akukho mntu uyawukwazi ukuba iinkcukacha nesithe sakufunda kusuka kuwe. Igama lakho aliyikubandakanywa kwiinkcukacha.

Oku sikufundayo kungasetyenziswa kuphela ukwenza iinkonzo zibengcono kwabasethyini bamaxhosa abaphila nentsholongwane kagawulayo nogawulayo. Uyakufowunelwa ucelwe ukuba uvume kwaye usayine (isivumo) ukuba iinkcukacha zibeluncedo ukusetyenziswa kwezinye izinto. Ukuba **unemibuzo okanye inkxalabo** nceda nxulumana no Kirsty Jackson (082 684 9760). Ungathumela umyalezo othi ndicela undifowunele ukunxulumana. Ungabuza imibuzo naninina nguthuba lesifundo.

Uvumelekile kananjalo ukunxulumana nomkhokeli mphandi okanye usihlalo we Human Research Ethics Committee ukuba nje unenkxalabo okanye imibuzo ngamalungelo akho okanye ukhuseleko njengabathathi nxaxheba.

Research supervisor:	**Human Research Ethics Committee Chairperson:**
Dr Romy Parker	Professor Marc Blockman
021 406 6571	021 406 6492

Appendix G/2: Information sheet – Therapeutic relationship Group

Information sheet – Therapeutic relationship Group

Study Title: **Efficacy of a multimodal approach to managing pain in rural amaXhosa women living with HIV/AIDS compared to a therapeutic relationship**

Name of researcher: Kirsty Jackson, Masters Physiotherapy Student BSc (Phys)
Name of supervisor:
Romy Parker, Bsc(Phys) Bsc(Med)(Hons) Ex.Sci(Phys) Msc(Pain) PhD(Psych)
Senior Lecturer and Deputy Head of Division (Physiotherapy)
Institution:
University of Cape Town, Division of Physiotherapy

What are we doing and why?

I am a student at the University of Cape Town. I'm doing a degree in MSc Physiotherapy. I want to learn about what helps amaXhosa women living with HIV/AIDS cope better. What helps you enjoy life more? What helps you do more activities? What helps you to take part in your family and community more. I want to find out whether being seen for follow-ups help you with the symptoms of HIV. To learn about this, we are asking some people to take part in this study. In the last few years a similar study was done in a South African city. The researcher found what seems to be a useful way of helping amaXhosa women in cities or towns cope more with living with HIV/AIDS. We now need more research to find out if this way will be useful here. Will this way be useful in rural amaXhosa women living with HIV/AIDS.

Why have you been asked?

You have shown interest in the study. You also meet the requirements which are needed to take part in the study. We are including people who are:

- amaXhosa
- HIV positive
- aged between 18 and 40 years
- attend one of the two clinics included in this study
- answered "yes" to the question: "Throughout our lives most of us have had pain from time to time (such as minor headaches, sprains, toothaches). Have you had pain other than these everyday kinds of pain during the last week?".

We are looking for 24 people from each clinic to take part.

What will taking part involve and what will you need to do?
If you agree to be part of the study you will first be asked questions. Then you will be asked to do a few actions or tasks. This should take 30-45 minutes. Your time is important and we understand that this is a long time. We will be very thankful for your time. It will help us to find out more about how we can help amaXhosa women living with HIV to cope better. Hopefully with time it will bring about change.

You have been placed in one of two groups. There was an equal chance of being put into either group. Each group will do something different. It doesn't matter which group you are in. We are doing the study to find out if either of the things the two groups do is better than the other. At the end of the study if what one group does is found to be better than you will have an opportunity to take part in what that group did.

You are in the group who will be seen by the same person at each follow-up date. You will be asked to come after 4 weeks, 8 weeks, 12 weeks, 24 weeks and 1 year after the study starts. We will need to talk to you and remind you of follow-up dates during the year. For this reason, we will ask for your cellphone number. During the study you must not tell anyone else that you are taking part in this group. You must not tell anybody what you are doing in the group. You must not tell people in the community or the person who sees you for follow-ups on how you are doing during the study.

What if something goes wrong
There is a chance that if you take part in this study somebody might find out that you have HIV. However, steps have been taken to prevent this. You will not meet at the clinic for follow-ups and your workbook does not have anything which is associated with HIV/AIDS.

We have promised that we will not give anyone your information. We will not share what you have told us with anyone else without asking you. There are only a few people who may see or hear what we have learnt from you. These people are the researcher, the research supervisor and members of the Human Research Ethics Committee. The Human Research Ethics Committee are a group of people who keep people taking part in studies safe. The researcher will not include your name or anything which identifies you when writing about what has been learnt.

You will also be protected if you have an injury during the study by the University of Cape Town (UCT). This is the institution behind the running of this study. UCT has insurance cover (money) to pay for medical costs if you get injured or have unpleasant side-effects because of taking part in this study. This plan has been made to follow the South African Good Clinical Practice Guidelines. These guidelines were written by the Department of Health in 2006. The ideas in these guidelines come from the Association of the British Pharmaceutical Industry Guidelines (ABPI). You will not have to show proof that the University is at fault for the injury. UCT will take responsibility without proof. You must immediately let the study health professional know if any injury happens to you during the study.

However, UCT **will not be responsible by law** in all situations. This means they do not have to pay for medical costs if the following happens:
Any loss, injuries and/or harm that happens to you because of

- The use of unauthorised medicine or substances (not having full permission or being allowed to use these) during the study
- Any injury that happens because you have not followed the rules or instructions that the study doctor/ health professional gives you
- Any injury that happens from not responding or acting on a side effect or reaction to the study medication as best as one can*
- An injury that happens from negligence (not taking proper care) on your part*

By taking part in the study you are still allowed to go the the law/ courts to claim for compensation. You can do this if an injury happens which you can prove was because of taking part in the study. This right will be protected and made sure of. Please be aware that most of the time you will be paid the money for to cover medical costs as a full settlement. This means that this will be the total money you will receive even if taken to court.

If you want further information about these guidelines you may ask for a copy.

What will taking part in this study help you with?
It is not clear exactly how the study will help you. This is why we are doing the study. We want to find out if these follow-ups help amaXhosa women with HIV in a rural context. We hope that the information learnt from this study will help people living with HIV/AIDS cope better in the future. If the results show how to help these people, then we would like to tell people who can change how the government and health care workers help HIV positive people. These people would include organisations, local health institutions, or government. All these people work together to help people living with HIV/AIDS. By sharing results, we can help them to improve services for people who are HIV positive to cope better. Your name and personal information will never be given to these organisations or government. Your name will always be kept safe.

Remember that if we find that one of the groups got more help from the study the other group will get offered that treatment. Therefore. if the study does have a benefit then you will have a chance to benefit from it.

Do you get anything if you commit to take part in the study?
You will not get money or get payed for taking part in the study. However, your transport costs to the hospital and back home will be paid for whenever you visit the clinic to take part in this study.

Taking part in this study is voluntary
It is your choice whether you would like to take part in this study or not. Nobody can tell you that you have to take part in the study. If you do agree and commit to take part in the study you will always have the choice to not answer questions asked. You cannot be forced to do tasks asked or come to follow-up dates. Your actions are your choice. Taking part is a choice during the whole study. If during the study you choose that you do not want to do something asked of you or you do not want to take part any longer you will not be treated any differently.

You will not be treated any differently if you decide not to be part of the study at all either. Those who take part in the study will not be given any privileges. They will not be treated differently in hospital and clinic services.

Will my information be safe?
The information you give us and what we learn from you will be kept safe. Nobody will be able to get that information except the researcher, research supervisor and members of the Human Research Ethics Committee. Other than these people nobody will know that the information and what we learn comes from you. Your name will not be included with information.

What we learn can only be used for making services better for amaXhosa women living with HIV/AIDS. You will be contacted and asked to agree and sign (consent) should the information be helpful for another use.

If you have **any questions or worries,** please contact Kirsty Jackson (082 684 9760). You may use a please-call me to make contact. You make ask questions at any time during the study.

You are also welcome to contact the research supervisor or the chairperson of Human Research Ethics Committee should you have concerns or questions about your rights or welfare as participants.

Research supervisor:

Dr Romy Parker
021 406 6571

Human Research Ethics Committee Chairperson:
Professor Marc Blockman
021 406 6492

Iphepha-nkcazelo – Therapeutic relationship Group

Isihloko sesifundo: **"Isifundo esifuna ukujonga ukuba iindlela ezohlukenenyo zokuncedisa ukumelana neentlungu ezifumaneka ngenxa yokuphila nogawulayo kwabasethyini bamaXhosa abaphila nentsholongwane kagawulayo okanye ugawulayo".**

Igama leresearcher: Kirsty Jackson, Masters Physiotherapy Student BSc (Phys)
Igama lesupervisor:
Dr. Romy Parker, Bsc(Phys) Bsc(Med)(Hons) Ex.Sci(Phys) Msc(Pain) PhD(Psych)
Senior Lecturer and Deputy Head of Division (Physiotherapy)
Iziko:
University of Cape Town, Division of Physiotherapy

Senza ntoni kwaye kutheni?

Ndingumfundi kwi dyunivesi yase Kapa. Ndenza imfundo enomsila kwiMSc Physiotherapy. Ndifuna ukufunda ngezinto ezingaba zinceda abasethyini bamaxhosa abaphila nentsholongwane kagawulayo/ugawulayo baphile ngcono. Yintoni ekuncedayo wonwabele ubom ngakumbi? Yintoni ekuncedayo ukwazi ukwenza imisebenzi eminintsi? Yintoni ekuncedayo ukwazi ukuthatha inxaxheba kusapho lwako nasekuhlaleni ngakumbi. Ndifuna ukufumanisa ukuba ngaba ukubonwa ngolandelelo kuyakunceda kwiimpawu zentsholongwane kagawulayo. Ukufunda ngoku sicela abanye babantu ukuba bathathe inxaxheba kwesisifundo. Umphandi ufumanise into engathi ingayindlela eluncedo yokunceda abasethyini bamaxhosa ezixekweni okanye ezidolophini bamelane ngakumbi nokuphila nentsholongwane kagawulayo okanye ugawulayo. Kengoku sidinga uphando olungakumbi ukufumanisa ukuba lendlela iyawuba luncedo na apha. Ingaba lendlela iyawuba luncedo kwabasethyini bamaxhosa abasemaphandleni abaphila nentsholongawane kagawulayo okanye ugawulayo.

Kutheni uceliwe?

Ubonakalise umdla kwisifundo. Kwaye unazo zonke izinto eziyimfuneko ukuze uthathe inxaxheba kwesisifundo. Siquka abantu aba:

- amaXhosa
- Abanentsholongwane kagawulayo
- Abaphakathi kweshumi elinesibhozo namashumi amane eminyaka.
- Abake beza kwenye yeekiliniki ezimbini eziqukwe kwesisifundo.
- Uphendule “ewe” embuzweni: “Kubo bonke ubom bethu abanintsi bentu bake baneentlungu kumaxesha ngamaxesha” (ezinjengentloko ebuhlungu engabhekele phi, Imisipha eqaqambayo, amazinyo aqaqmbayo).Uke wanazo iintlungu ngaphandle kwezi zamihla yonke kwezinyanga zintathu zidlulileyo?.

Sikhangela abantu abangamashumi amabini anesine kwikiliniki nganye ukuba bathathe inxaxheba.

Igaba kuyawuquka ntoni oku kuyawube kusenzeka kwaye kuyawufuneka wenze ntoni?

Ukuba uyavuma ukuba yinxalenye yesifundo uyawuqale ubuzwe imibuzo. Uze ucelwe kengoku ukuba wenze iintshukumo ezimbalwa okanye imisebenzi. Oku kumele kuthathe imizuzu engamashumi amathathu ukuya kumashumi amane anesihlanu emizuzu. Ixesha lakho libalulekile kwaye siyaqonda ukuba lixesha elide eli. Siyawukulibulela kakhulu ixesha lakho. Kuyawusinceda sifumanise ngakumbi ukuba singabanceda njani abasetyhini bamaxhosa abaphila nentsholongwane kagawulayo baphile ngcono. Ethembeni ekuhambeni kwexesha iyawuzisa uthsintsho.

Ubekiwe kwelinye lamaqela amabini. Bekukho amathuba alinganayo okuba ubekwe nakweliphi na iqela. Iqela ngalinye liyawukwenza into eyahlukileyo. Akukhathaliseki ukuba ukweliphi iqela. Senza isifundo ukufumanisa ukuba ngaba enye yenzinto zenziwa ngalamaqela mabini ingcono kunenye. Ekupheleni kwesifundo ukuba into eyenziwa lelinye iqela ifumaniseke ingcono ngoko uyawuba nethuba lokuba uthabathe inxaxheba kwinto eyenziwa leloqela.

Useqeleni eliyawukubonwa ngumntu omnye kuzo zonke iintsuku zodibana. Uyawucelwa ukuba uze emva kweeveki ezine, ezisibhozo, ezilishumi elinambini, ezingamashumi mabini anesine kunye nonyaka emva kokuba isifundo siqalile.

Kuyawufuneka sithethe nawe kwaye sikukhumbuze ngeentsuku zolandelelwa enyakeni. Ngenxa yesisizathu siyawucela inombolo yakho yomnxeba.

Ngethuba lesifundo ungamxeleli umncedisi owenza imibuzo novavanyo kuwe ukuba ukwekiphi iqela. Ungabaxeleli ukuba ukwiqela leTherapeutic.

Ukuba kukho into ehambe ngedlela engeyiyo?

Kukho ithuba lokuba ukuba uthabatha inxaxheba kwesisifundo omnye umntu angafumanisa ukuba unentsholongwane kagawulayo. Sekunjalo amanyathelo athathiwe ukuthintela oko. Anizudibana kwiikliniki zamachiza entsholongwane kagawulayo ngeentsuku zokulandelelwa kwaye nencwadi yenu yokusebenzela ayinayo kwanto enxulumene nentsholongwane kagawulayo okanye ugawulayo.

Sithembisile ukuba asisayi kunika mntu iinkcukacha zakho. Asisayi kwabelana namntu ngothe wasixelela kona ngaphandle kokuba sicele okanye sibuze kuwe. Kukho abantu abambalwa abangabona okanye beve ngesithe sakufunda kuwe. Ababantu ngabaphandi, umkhokeli phando namalungu eHuman Research Ethic Committee. iHuman Research Ethic Committee liqela labantu abagcina abantu abathatha inxaxheba esifundweni bekhuselekile. Umphandi akasayi kuquka igama lakho okanye nantoni na eyakuchaza wena xa ebhala ngokuthe kwafundwa.

Uyawukhuseleka kananjalo ukuba uthe wafumana umonzakalo ngethuba lesifundo esenziwa yidyunivesiti yase Kapa (UCT). Eli liziko elimelene nokuqhuba kwesisifundo. I UCT inombutho (wemali) wokubhatala iindleko zonyango ukuba uthe wafumana umonzakalo okanye ubenemiphumela engaqhelekanga ngenxa yothatha inxaxheba kwesisifundo. Elicebo lenzelwe ukulandela I South African Good Clinical Practice Guidelines. Lemigaqo yabhalwa lisebe lezempilo ngo 2006. Iingcamango ngalomgaqo yasuka kwi Association of the British Pharmaceutical Industry Guidelines (ABPI). Awusayi kufuneka ukuba uveze ubungqina bokuba idyunivesi isengxakini ngenxa yomonzakalo. I UCT iyawuthatha uxanduva ngaphandle kobungqina. Kuyawufuneka ngokukhawuleza wazise ingcali yezifundo zezempilo ukuba kukho umonzakalo owenzeke kuwe ngethuba lesifundo.

Sekunjalo I UCT **ayiwubanaxanduva ngokomthetho** kuzo zonke iimeko. Oku kuthetha ukuba abafanelanga ukuba babhatale iindleko zonyango ukuba kwenzeke oku kulandelayo:

Nakuphi na ukulahlekelwa, Umonzakalo okanye ingozi ethe yenzeka kuwe ngenxa :

- Yokusebenzisa amachiza angavumelekanga okanye izinto (ukungabinamvume epheleleyo okanye ungavumelekanga usebenzise ezonto ngexesha lesifundo.
- Nawuphi na umonzakalo othe wenzeka ngenxa yokuba ungalandelanga imithetho okanye imiyalelo athe ugqirha wesifundo okanye ingcali yezempilo yakunika yona.
- Nawuphi na umonzakalo othe wenzeka ngokungalandeli okanye wenze.
- Nayipi na ingozi eyenzeke ngokungalandeli okanye ukwenza intshukumo ekhawulezileyo xa ubona ukuba amayeza owanikiweyo awakulungeli.
- Nawuphi na umonzakalo othe wenzeka ngenxa yokungabinankathalo(ukungakhathali ngokupheleleyo) kwindima yakho.

Ngokuthatha inxaxheba kwisifundo usavumelelkile ukuba uye emthethweni okanye enkudleni uyokwenza ibango lomonzakalo. Ungakwenza oku xangaba umonzakalo othe wenzeka unganobungqina bokuba wenzeke ngenxa yothatha inxaxheba kwisifundo. Ilungelo lakho liyakukhuseleka kwaye liqinisekiswe. Nceda qaphela ukuba amaxesha amanintsi uyawubhatalwa imali ukuze uhlawule zonke iindleko zonyango ngokuphelelelyo. Oku kuthetha ukuba le yimali ephelelyo oyakuyibhatalwa noba ungasisa enkundleni.

Ukuba ufuna iingcombolo ezingakumbi ngalemigaqo ungacela ikopi.

Kuyakunceda ngantoni uthatha inxaxheba kwesisisfundo?

Akucacanga ncam ukuba isifundo siyakunceda kanjani. Yiyo loonto sisenza isifundo. Sifuna ukufumananisa ukuba ngaba iindibano ziyabanceda abasethyini bamaxhosa abaphila nentsholongwane kagawulayo abakwingingqi zasemaphandleni. Siyathemba ukuba iinkcukacha esithe sazifunda kwesisifundo ziyawukubanceda abantu abaphila nentsholongwane kagawulayo baphile ngcono ebomini. Ukuba iziphumo zibonisa ukuba singabanceda njani ababantu ngoko singathanda ukuxelela abantu abanotshintsha indlela urhulumente nabancedisi bamaziko empilo abanceda ngayo abantu abanentsholongwane kagawulayo. Ababantu bayawuquka imibutho, amaziko empilo asekuhlaleni, okanye urhulumente. Bonke ababantu bayasebenzisana ukuncceda abantu abaphila nentsholongwane kagawulayo nogawulayo. Ngokwabelana ngeziphumo singabanceda baphucule iinkonzo kubantu abanentsholongwane kagawulayo baphile ngcono. Igama lakho okanye iingcombolo ngawe azisayi kunikezelwa kulemibutho okanye kerhulumente. Igama lakho liyakuhlala ligcinwe likhuselekile.

Khumbula ukuba sithe safumanisa ukuba elinye lamaqela lifumene lukhulu kwisifundo elinye iqela liyakunikezwa olonyango. Ngoko ke ukuba isifundo sithe saxhamla ngoko uyawufumana ithuba loxhamla kubo.

Kukho into oyifumanayo ukuba uyazibophelela uthatha inxaxheba kwisifundo

Awusayi kufumana mali okanye ubhatalwe ngothatha inxaxheba kwisifundo. Kodwa ke iindleko zakho zokhwela isithuthi xa usiza esibhedlele nobuyela ekhaya ziyakubhatalwa ngalo lonke ixesha undwendwela ekiliniki uzothatha inxaxheba kwisifundo.

Uthatha inxaxheba kwesisifundo kuzinikela

Lukhetho lwakho ukuba uyawuthatha inxaxheba kwesisifundo okanye hayi. Akukho mntu onokuxelela ukuba uthathe inxaxheba kwisifundo. Ukuba uyavuma kwaye uyazibophelela uthatha inxaxheba kwisifundo ngalolonke ixesha uyawuba nokhetho lokuba ungaphenduli imibuzo ebuziweyo. Awunakunyanzelwa ukuba wenze imisebenzi okanye ukuza kwiintsuku zophinda ubonwe. Iintshukumo zakho lukhetho lwakho. Uthatha inxaxheba kuzikhethela ngalo lonke ithuba lesifundo. Ukuba ngethuba lesifundo ukhetha ukuba awusafuni ukuthatha inxaxheba awusayi kuphathwa ngendlela eyahlukileyo.

Awusayi kuphathwa ngokwahlukileyo ukuba ugqiba ekubeni ungabiyiyo inxalenye yesifundo kwawena. Abo bathatha inxaxheba esifundweni abayi kunikwa ngqwalasela. Abayi kuphathwa ngokwahlukileyo esibhedlele nasekiliniki.

Ingaba iinkcukacha ngam ziyawukhuseleka?

Iinkcukacha osinike zona ngawe nesithe sakufunda kuwe kuyawugcinwa kukhuselekile. Akukho mntu uyawukwazi ukufumana ezonkcukacha ngaphandle komphandi, umkhokeli mphandi namalungu e Human Research Ethics Committee. Ngaphandle kwababantu akekho omnye oyawukwazi ukuba iinkcukacha ngawe nesithe sakufunda kusuka kuwe. Igama lakho alisayi kubandakanywa kwiinkcukacha.

Oku sithe sakufunda kungasetyenziswa kuphela ukwenza iinkonzo ngcono kwabasetyhini bamaxhosa abaphila nentsholongwane kagawulayo okanye ugawulayo. Uyakutsalelwa umnxeba ucelwe ukuba uvume utyikitye ifomu yokuzibophelela ukuba iinkcukacha zithe zalulutho ukuba zisetyenziselwe okunye.

Ukuba **unawo nawuphi na umbuzo okanye inkxalabo** nceda unxulumane noKirsty Jackson (082 684 9760). Ungenza umyalezo ocela ufowunelwa (Please call me) ukunxulumana. Ungabuza umbuzo ngalo naliphina ixesha ngethuba lesifundo.

Kananjalo wamnkelekile ukuba unganxulumana nomkhokeli mphandi okanye usihlalo we chairperson of Human Research Ethics Committee ukuba unenkxalabo okanye imibuzo malunga namalungelo akho okanye ukhuseleko lwakho njengomthathi nxaxheba.

Research supervisor:	**Human Research Ethics Committee Chairperson:**
Dr Romy Parker	Professor Marc Blockman
021 406 6571	021 406 6492

Appendix G/3: Informed consent form

School of Health & Rehabilitation Sciences
Divisions of Communication Sciences & Disorders ·
Nursing & Midwifery · Occupational Therapy · Physiotherapy

Informed consent form

Dear participant

You are invited to take part in the study on:

> "Efficacy of a multimodal approach to managing pain in rural amaXhosa women living with HIV/AIDS compared to a therapeutic relationship".

Please read or have the information sheet read to you before you choose to sign this form. We hope that this study can help us to learn more about how to help rural amaXhosa women who are HIV positive cope better with living with HIV.

I, _____, have read and understood all of what is written in the information sheet. (And I have been read all of what is written in the information sheet by _____). I know why the study is being done and what the study involves. I also know what may be unsafe and what may be helpful in taking part. I have had all of my questions and worries listened to and answered. I may ask any questions or voice any worries I might have in the future. I know that at any time I am allowed to stop taking part in the study. This will not change the normal treatment I get at hospital or clinic services.

I know that by signing here (giving consent) I am choosing by myself to take part in this study. I know that if I do not want to answer questions or do tasks asked of me I do not have to.

Signed:

_____ _____

Participant (name and signature) Date and place

_____ _____

Researcher (name and signature) Date and place

_____ _____

Witness (name and signature) Date and place

School of Health & Rehabilitation Sciences
Divisions of Communication Sciences & Disorders ·
Nursing & Midwifery · Occupational Therapy · Physiotherapy

Informed consent form

Mholo mthathinxaxheba

Uyamenywa ukuba uthathe inxaxheba kwesisifundo singe:

> **“Isifundo esifuna ukujonga ukuba iindlela ezohlukenenyo zokuncedisa ukumelana neentlungu ezifumaneka ngenxa yokuphila nogawulayo kwabasethyini bamaXhosa abaphila nentsholongwane kagawulayo okanye ugawulayo”.**

Nceda ufunde okanye ufundelwe umqulu oneenkcukacha phambi kokuba ukhethe ukutyikitya lefomu. Siyathemba ukuba esisifundo siyawusinceda ukuba sifunde ngakumbi ngokuba singabanceda kanjani abasethyini bamaxhosa abasemaphandleni abanentsholongwane bamelane ngcono nokuphila nogawulayo.

Mna, _____ , ndikufundile kwaye ndakuqonda konke okubhalwe kulomqulu. . (Kwaye ndikufundelwe konke okubhalwe kulomqulu oneenkcukacha ndifundelwa ngu _____). Ndiyazi ukuba kutheni isifundo sisenziwa kwaye siquka ntoni isifundo. Ndiyazi kananjalo ukuba yintoni engagakhuseleki nokuba yintoni engaluncedo ekuthatheni inxaxheba. Yonke imibuzo yam neekxalabo zimanyelwe kwaye zaphendulwa. Ndingabuza nayiphi na imibuzo okanye ndivakalise inkxalabo endingaba nayo ekuhambeni kwexesha. Ndiyazi ukuba ndivumelekile ukuba nangaliphi na ixesha ndivumelekile ukuba ndinganqumama ukuthatha inxaxheba kwisifundo. Oku akusayi kutshintsha indlela eqhelekileyo yonyango endilufumanayo esibhedlele okanye ekiliniki.

Ndiyazi ukuba ngokutyikitya apha(unikeza isivumelwano sokuzibophelela) ndiyazikhethela ukuthabatha inxaxheba kwesisifundo. Ndiyazi ukuba, ukuba andifuni ukuphendula imibuzo okanye ndenze izinto endicelwe ukuba ndizenze andinyanzelekanga.

Isayinwe:

_____	_____
Umthathi nxaxheba (Igama nesayinwe)	Umhla nendawo
_____	_____
Umphandi (Igame nesayinwe)	Umhla nendawo
_____	_____
Ingqina (igame nesayinwe)	Umhla nendawo

Appendix H: Post Study Structured Interviews

Appendix H/1: Post Study Structured Interview for Positive Living Group Participants

Allocated no: _____

1. Did you find the group sessions useful?
□ Yes □ No

Please explain:
_____
_____
_____

2. Is there any other information that you feel should have been included in the sessions?
□ Yes □ No

Please explain:
_____
_____
_____

3. Did you read the workbook given to you or have somebody read it to you?
□ Yes □ No

Please explain:
_____
_____
_____

4. Did you find the information in the workbook useful?
□ Yes □ No

Please explain:
_____
_____
_____

5. Is there any other information that you feel should have been included in the workbook?

□ Yes □ No

Please explain:

_____
_____
_____

6. Did you share or discuss any of the information with anybody else?

□ Yes □ No

If yes, then with you. Please explain:

_____
_____
_____

7. Is there anything else that you would like to share?

_____
_____
_____

Appendix H/2: Post Study Structured Interview for Therapeutic Group Participants

Allocated no: _____

1. Did you receive any information during the study about HIV/ADS that helped you to manage your symptoms?

□ Yes □ No

Please explain:

_____
_____
_____

2. Did you discuss ways to manage your symptoms with others?

□ Yes □ No

If yes, then with whom?

_____
_____
_____

Appendix I: Ethics Approval Letters

Appendix I/1: Letter of approval from the Human Resource Ethics Committee, Faculty of Health Sciences, University of Cape Town: HREC REF: 932/2014

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E52-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6338 • **Facsimile** [021] 406 6411
Email: shuretta.thomas@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

17 December 2014

HREC REF: 932/2014

Dr R Parker
Health & Rehab
F45, OMB

Dear Dr Parker

PROJECT TITLE: EFFICACY OF A MULTIMODAL APPROACH TO MANAGING PAIN IN RURAL AMAXHOSA WOMEN LIVING WITH HIV/AIDS COMPARED TO A THERAPEUTIC RELATIONSHIP (MSc candidate - K Jackson)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30th December 2015.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF in all your correspondence.

We acknowledge that the student, Kirsty Jackson will also be involved in this study.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Yours sincerely

Signed

pp

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP) and Declaration of Helsinki guidelines.

HREC 932/2014

The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/**95**) and FDA Code Federal Regulation Part 50, 56 and 312.

HREC 932/2014

Appendix I/2: Letter of approval from the Eastern Cape Department of Health

Eastern Cape Department of Health

Enquiries:	Zonwabele Merile	Tel No:	040 608 0830
Date:	28th January 2015	Fax No:	043 642 1409
e-mail address:	zonwabele.merile@impilo.ecprov.gov.za		

Dear Ms Kirsty Jackson

Re: Efficacy of a multimodal approach to managing pain in rural amaXhosa women living with HIV/AIDS compared to a therapeutic relationship (Ref. EC_2015RP30_713)

The Department of Health would like to inform you that your application for conducting a research on the abovementioned topic has been approved based on the following conditions:

1. During your study, you will follow the submitted protocol with ethical approval and can only deviate from it after having a written approval from the Department of Health in writing.
2. You are advised to ensure, observe and respect the rights and culture of your research participants and maintain confidentiality of their identities and shall remove or not collect any information which can be used to link the participants.
3. The Department of Health expects you to provide a progress on your study every 3 months (from date you received this letter) in writing.
4. At the end of your study, you will be expected to send a full written report with your findings and implementable recommendations to the Epidemiological Research & Surveillance Management. You may be invited to the department to come and present your research findings with your implementable recommendations.
5. Your results on the Eastern Cape will not be presented anywhere unless you have shared them with the Department of Health as indicated above.

Your compliance in this regard will be highly appreciated.

Signed

SECRETARIAT: EASTERN CAPE HEALTH RESEARCH COMMITTEE

PGDP EASTERN CAPE 2004 - 2014

Ikamva eliqaqambileyo!

Appendix I/3: Permission for research from Zithulele Hospital, Eastern Cape, Department of Health

ZITHULELE HOSPITAL

Province of the Eastern Cape • Iphondo leMpuma-Koloni
Department of Health • Isebe leZempilo

Enquiries: Dr CB Gaunt

Ref: Jackson K – research permission

Date: 16 January 2015

P Bag X504, Mqanduli, 5080
Tel: 047-5738935
Fax to email: 086-6165457
Cell: 072-2630333
Email: ben@zithulele.org
www.zithulele.org

Faculty of Health Sciences
Human Research Ethics Committee
University of Cape Town

Dear Research Ethics Committee

PERMISSION FOR RESEARCH: MS KIRSTY JACKSON

I give permission for the study 'Efficacy of a multimodal approach to managing pain in rural amaXhosa women living with HIV/AIDS compared to education or a therapeutic relationship' by Ms Kirsty Jackson. I permit access to the nursing and medical staff in order to conduct the study and am happy that our patients will potentially benefit and not be harmed from the proposed intervention being studied.

We look forward to learning of the outcomes of this research and hope it will lead to improvements in the care of people living with HIV in our community.

Yours sincerely

Signed

Dr Ben Gaunt
Clinical Manager
Zithulele Hospital

Appendix I/4: Ethics approval renewal (2015 - 2016)

HUMAN RESEARCH ETHICS COMMITTEE
09 NOV 2015
HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN

UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938) This serves as notification of annual approval, including any documentation described below.			
☑ Approved	Annual progress report	Approved until/next renewal date	30.11.2016
☐ Not approved	See attached comments		
Signature Chairperson of the HREC	Signed	Date Signed	11/11/2015

Comments to PI from the HREC

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	4 November 2015		
HREC REF Number	932/2014	Current Ethics Approval was granted until	30/12/2015
Protocol title	Efficacy of a multimodal approach to managing pain in rural amaXhosa women living with HIV/AIDS compared to a therapeutic relationship		
Protocol number (if applicable)	PACTR201410000902600		
Are there any sub-studies linked to this study?	☐ Yes x No		
If yes, could you please provide the HREC Ref's for all sub-studies? **Note:** A separate FHS016 must be submitted for each sub-study.			
Principal Investigator	Dr. Romy Parker		
Department / Office Internal Mail Address	Health and Rehabilitation Sciences romy.parker@uct.ac.za		

1.1 Does this protocol receive US Federal funding?	☐ Yes	x No
1.2 If the study receives US Federal Funding, does the annual report require full committee approval?	☐ Yes	☐ No N/A
1.3 Has sponsorship of this study changed? If yes, please attach a revised summary of the budget.	☐ Yes	x No

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

2. List of documentation for approval

N/A

3. Protocol status (tick ✓)

☐	Open to enrolment
✓	Closed to enrolment (tick ✓)
✓	Research-related activities are ongoing
✓	Research-related activities are complete, long-term follow-up only
☐	Research-related activities are complete, data analysis only
☐	Main study is complete but sub-study research-related activities are ongoing
☐	Study is closed → Please submit a Study Closure Form (FHS010)

4. Enrolment

Number of participants enrolled to date	51
Number of participants enrolled, since last HREC Progress report (continuing review)	51
Additional number of participants still required	0

5. Refusals

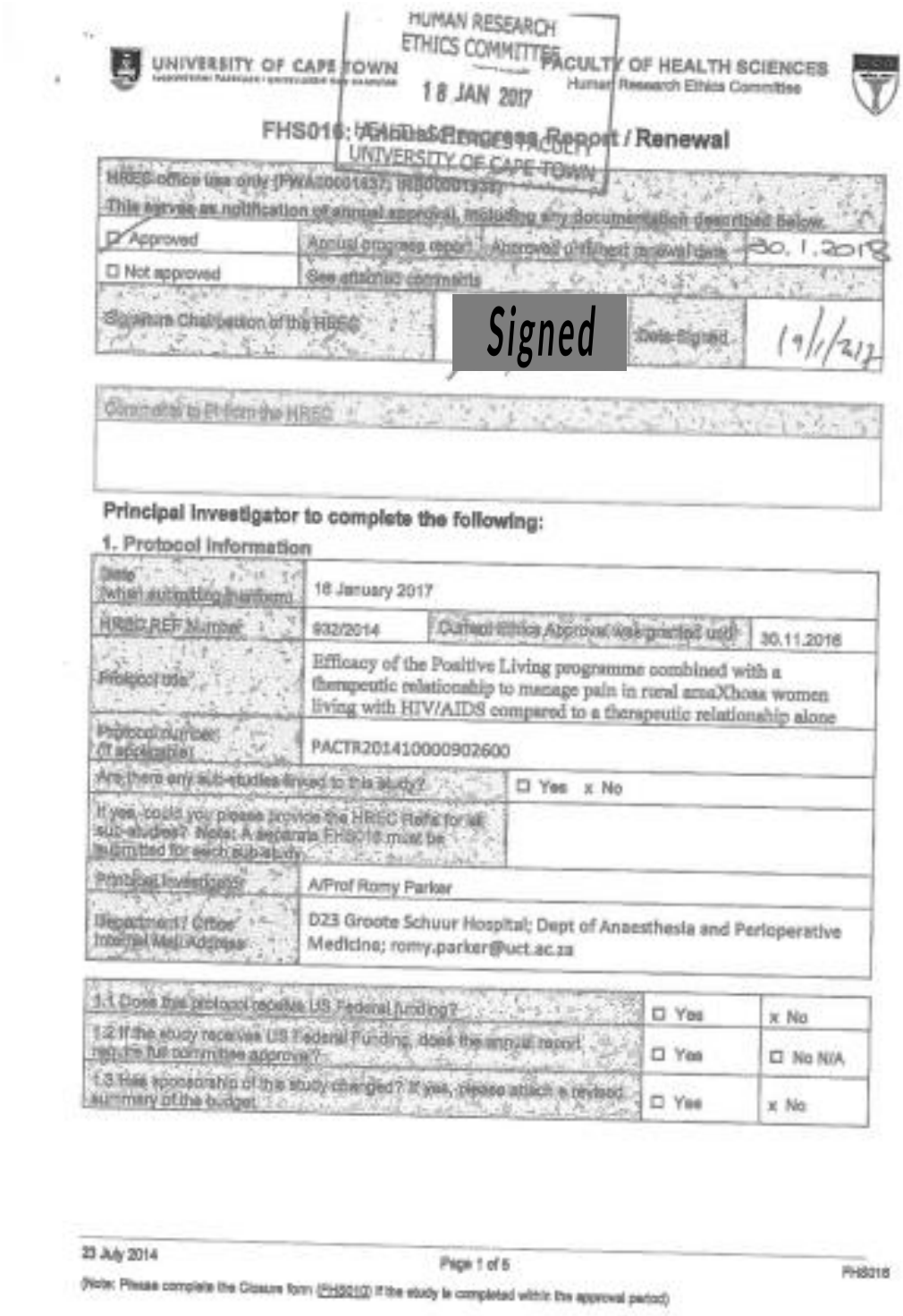
Total number of refusals (participants invited to join the study, but refused to take part)	22

6. Cumulative summary of participants

Total number of participants who provided consent	51
Number of participants determined to be ineligible (i.e. after screening)	33
Number of participants currently active on the study	45
Number of participants completed study (without events leading to withdrawal)	incomplete
Number of participants withdrawn at participants' request (i.e. changed their mind)	0
Number of participants withdrawn by PI due to toxicity or adverse events	0
Number of participants withdrawn by PI for other reasons (e.g. pregnancy, poor compliance)	0
Number of participants lost to follow-up. Please comment below on reasons for loss of follow-up.	2
Did not return for intervention/follow-up after baseline. Consented to calls to remind participant of dates but only reaching voicemail.	
Number of participants no longer taking part for reasons not listed above. Please provide reasons below:	2
Started working Moved to further away	

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

Appendix I/5: Ethics approval renewal (2016 - 2017)



UNIVERSITY OF CAPE TOWN

HUMAN RESEARCH ETHICS COMMITTEE
18 JAN 2017
FACULTY OF HEALTH SCIENCES
UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

FHS016: Ethics Progress Report / Renewal

HREC office use only (FWA00001437; IRB00001938)	
This serves as notification of annual approval, including any documentation described below.	
☑ Approved	Annual progress report - Approval of latest renewal date: 30.1.2018
☐ Not approved	See attached comments
Signature Chairperson of the HREC	Signed — Date Signed: 19/1/17

Comments to PI from the HREC

Principal Investigator to complete the following:

1. Protocol Information

Date (when submitting this form)	18 January 2017		
HREC REF Number	932/2014	Current Ethics Approval was granted until	30.11.2016
Protocol title	Efficacy of the Positive Living programme combined with a therapeutic relationship to manage pain in rural amaXhosa women living with HIV/AIDS compared to a therapeutic relationship alone		
Protocol number (if applicable)	PACTR201410000902600		
Are there any sub-studies linked to this study?	☐ Yes x No		
If yes, could you please provide the HREC Refs for all sub-studies? Note: A separate FHS016 must be submitted for each sub-study			
Principal Investigator	A/Prof Romy Parker		
Department/ Office/ Internal Mail Address	D23 Groote Schuur Hospital; Dept of Anaesthesia and Perioperative Medicine; romy.parker@uct.ac.za		

1.1 Does the protocol receive US Federal funding?	☐ Yes	x No
1.2 If the study receives US Federal Funding, does the annual report go to the full committee approval?	☐ Yes	☐ No N/A
1.3 Has sponsorship of the study changed? If yes, please attach a revised summary of the budget	☐ Yes	x No

23 July 2014 — Page 1 of 5 — FHS016

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

Appendix I/6: Pan African Clinical Trial Registry: PACTR201410000902600

SOUTH AFRICAN COCHRANE CENTRE

PO Box 19070, Tygerberg, 7505, South Africa;
Francie van Zijl Drive, Parow Valley, Cape Town
Tel: +27 21 938 0438; Fax: +27 21 938 0836
E-mail: cochrane@mrc.ac.za

30 October 2014

To Whom It May Concern:

RE: A comparison of non-pharmacological interventions for reducing pain in individuals with HIV.

As project manager for the Pan African Clinical Trial Registry (www.pactr.org) database, it is my pleasure to inform you that your application to our registry has been accepted. Your unique identification number for the registry is **PACTR201410000902600**

Please be advised that you are responsible for updating your trial, or for informing us of changes to your trial.

Additionally, please provide us with copies of your ethical clearance letters as we must have these on file (via email, post or fax) at your earliest convenience if you have not already done so.

Please do not hesitate to contact us at +27 21 938 0835 or email epienaar@mrc.ac.za should you have any questions.

Yours faithfully,

Elizabeth D Pienaar
www.pactr.org Project Manager
+27 021 938 0835

PACTR
PAN AFRICAN CLINICAL TRIALS REGISTRY

Appendix J: Supplementary results

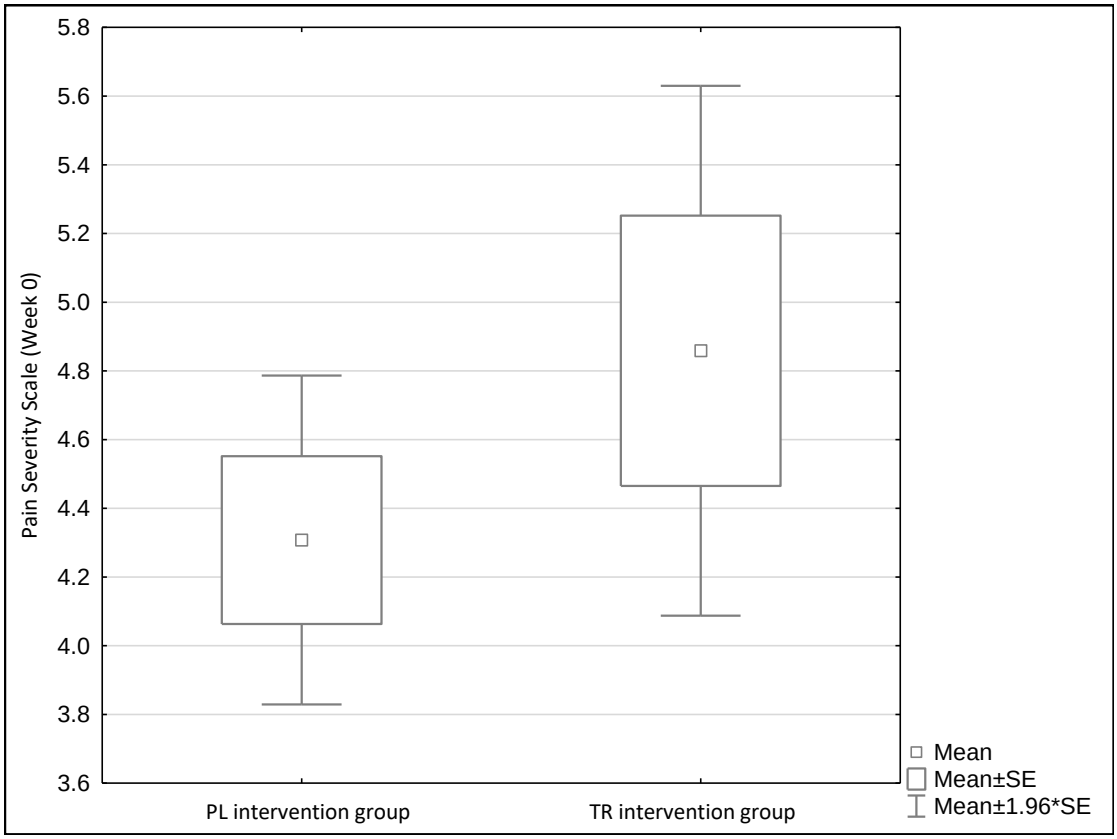


Figure F-1: Pain Severity Scores at Baseline for the PL and TR intervention groups (N = 49)

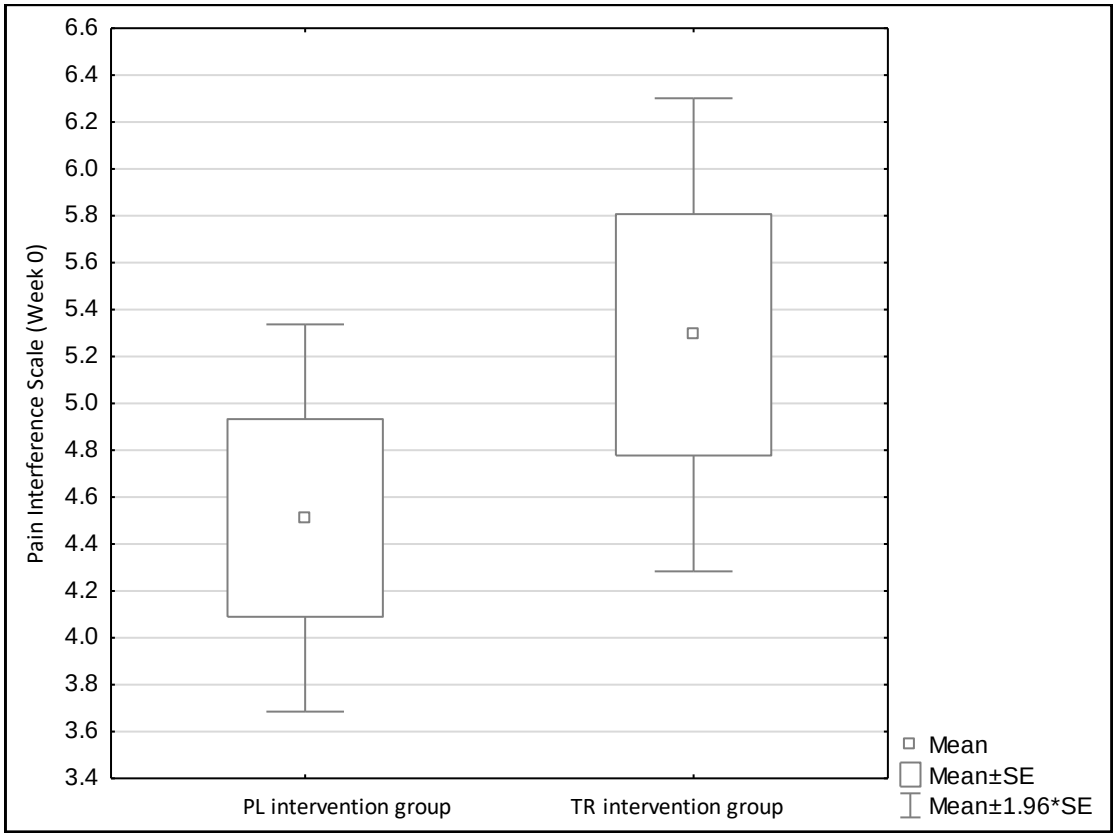


Figure F-2: Pain Interference Scores at Baseline for the PL and TR intervention groups (N = 48)

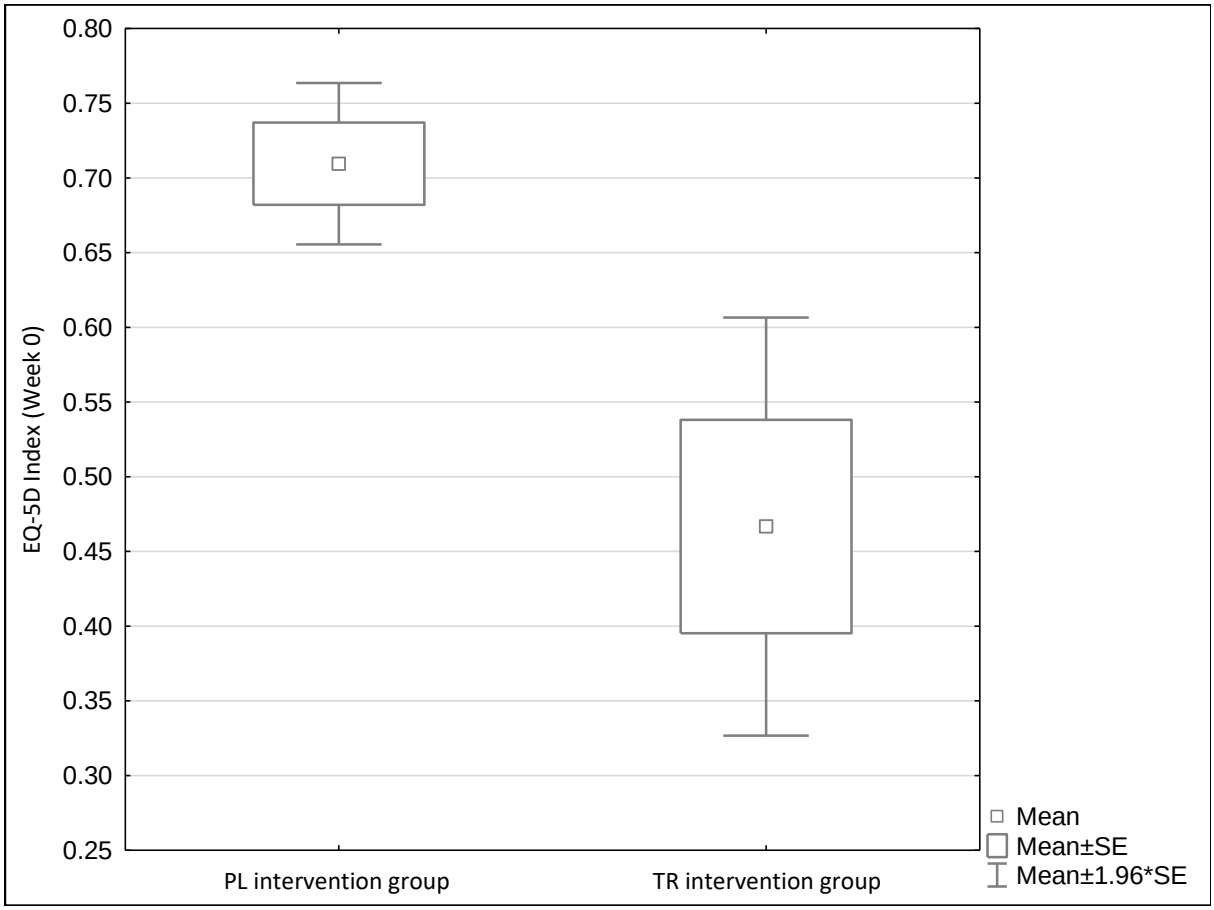


Figure F-3: EQ-5D Index at Baseline for the PL and TR intervention goups (N = 49)

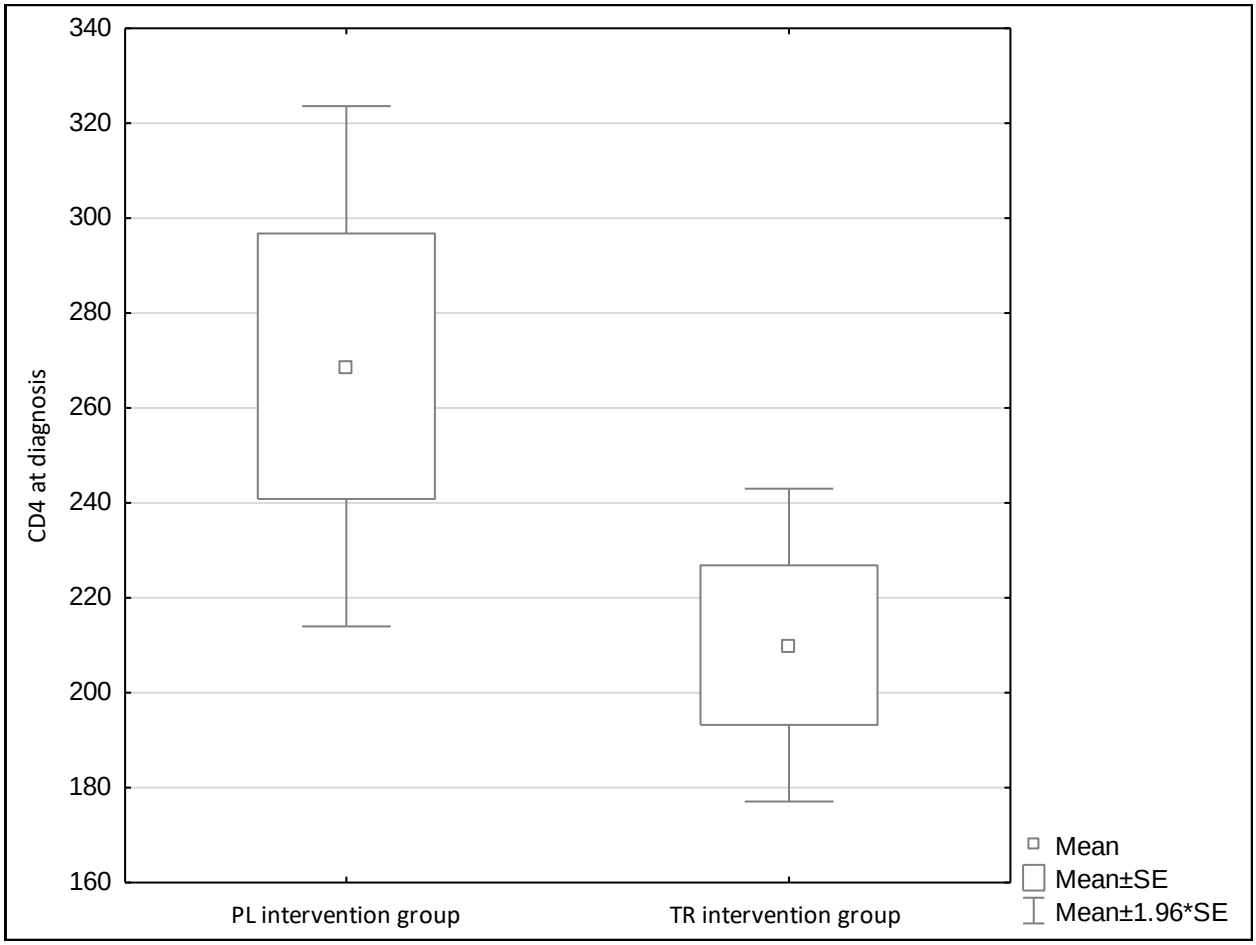


Figure F-4: Results collected at Baseline of CD4 T-cell count at diagnosis for the PL and TR intervention groups (N = 39)

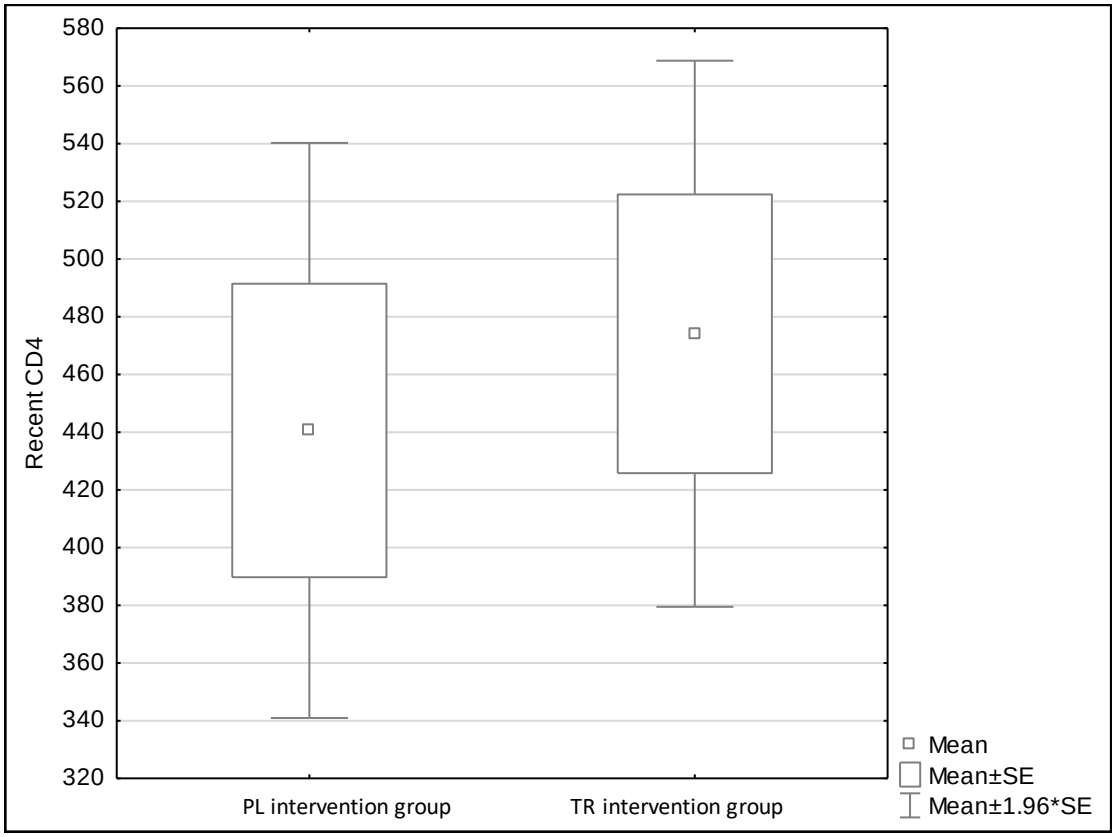


Figure F-5: Results collected at Baseline of the most recent CD4 T-cell count for the PL and TR intervention groups (N = 45)

Appendix K: CONSORT Guidelines and indication of chapter where items were addressed

Section/Topic	Item No	Checklist item	Reported in
Title and abstract	1b	Identification as a randomised trial in the title Structured summary of trial design, methods, results, and conclusions	Abstract
Introduction	2a	Scientific background and explanation of rationale	Chapter 1 and 2.1
Background/objective	2b	Specific objectives or hypotheses	Chapter 1.5
Methods			
Trial design	3a 3b	Description of trial design (such as parallel, factorial) including allocation ratio Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Chapter 3.1
Participants	4a 4b	Eligibility criteria for participants Settings and locations where the data were collected	Chapter 3.2 Chapter 3.4 and 3.7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Chapter 3.6 and Appendix B
Outcomes	6a 6b	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed Any changes to trial outcomes after the trial commenced, with reasons	Chapter 3.5 and Appendix A Chapter 3.7
Sample size	7a 7b	How sample size was determined When applicable, explanation of any interim analyses and stopping guidelines	Chapter 3.3
Randomisation: **Sequence generation**	8a 8b	Method used to generate the random allocation sequence Type of randomisation; details of any restriction (such as blocking and block size)	N/A (stratified) Chapter 3.1 and 3.7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	N/A (stratified) Chapter 3.1 and 3.7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Chapter 3.7
Blinding	11a 11b	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how If relevant, description of the similarity of interventions	Chapter 3.7

Section/Topic	Item No	Checklist item	Reported in
Statistical methods	12a 12b	Statistical methods used to compare groups for primary and secondary outcomes Methods for additional analyses, such as subgroup analyses and adjusted analyses	Chapter 3.9
Results			
Participant flow (a diagram is strongly recommended)	13a 13b	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome For each group, losses and exclusions after randomisation, together with reasons	Chapter 4.1 and Figure 4-1 and 4-2
Recruitment	14a 14b	Dates defining the periods of recruitment and follow-up Why the trial ended or was stopped	Chapter 4.1
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 4-1 and 4-2 (Chapter 4.2) Table 4-3 – 4-7 (Chapter 4.3)
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Figure 4.1 and Chapter 4
Outcomes and estimation	17a 17b	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Chapter 4.4 – 4.8
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Chapter 4.2 – 4.9
Harms	19	All important harms or unintended effects in each group	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Chapter 5.8.2
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Chapter 5.8.2
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Chapter 5

Section/Topic				Item No
Other information				
Registration	23	Registration number and name of trial registry	Pan African Clinical Trial Registry (PACTR201410000902600)	
Protocol	24	Where the full trial protocol can be accessed, if available	N/A	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Acknowledgements	